Office of the Secretary Of Defense (OSD)
Deputy Director of Defense Research & Engineering
Deputy Under Secretary of Defense (Science & Technology)
Small Business Innovation Research (SBIR)
FY2009.3 Program Description

Introduction

The Deputy Under Secretary of Defense (Science & Technology) SBIR Program is sponsoring the Defense Health Program Biomedical Technology theme in this solicitation.

The Army, Navy, and Air Force are participating in the OSD SBIR Program on this solicitation. The service laboratories act as our OSD Agent in the management and execution of the contracts with small businesses. The service laboratories, often referred to as a DoD Component acting on behalf of the OSD, invite small business firms to submit proposals under this Small Business Innovation Research (SBIR) Program solicitation. In order to participate in the OSD SBIR Program this year, all potential proposers should register on the DoD SBIR Web site as soon as you can, and should follow the instruction for electronic submittal of proposals. It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Web site at http://www.dodsbir.net/submission. If you experience problems submitting your proposal, call the help desk (toll free) at 1-866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit of 25 pages. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The DoD SBIR Proposal Submission Web site allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report.

We WILL NOT accept any proposals that are not submitted through the on-line submission site. The submission site does not limit the overall file size for each electronic proposal, there is only a 25-page limit. However, file uploads may take a great deal of time depending on your file size and your internet server connection speed. If you wish to upload a very large file, it is highly recommended that you submit prior to the deadline submittal date, as the last day is heavily trafficked. You are responsible for performing a virus check on each technical proposal file to be uploaded electronically. The detection of a virus on any submission may be cause for the rejection of the proposal. We will not accept e-mail submissions.

Firms with strong research and development capabilities in science or engineering in any of the topic areas described in this section and with the ability to commercialize the results are encouraged to participate. Subject to availability of funds, the DUSD(S&T) SBIR Program will support high quality research and development proposals of innovative concepts to solve the listed defense-related scientific or engineering problems, especially those concepts that also have high potential for commercialization in the private sector. Objectives of the DUSD(S&T) SBIR Program include stimulating technological innovation, strengthening the role of small business in meeting DoD research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, and increasing the commercial application of DoD-supported research and development results. The guidelines presented in the solicitation incorporate and exploit the flexibility of the SBA Policy Directive to encourage proposals based on scientific and technical approaches most likely to yield results important to DoD and the private sector.

Description of the OSD SBIR Three Phase Program

Phase I is to determine, insofar as possible, the scientific or technical merit and feasibility of ideas submitted under the SBIR Program and will typically be one half-person year effort over a period not to exceed six months, with a dollar value up to $100,000. We plan to fund 3 Phase I contracts, on average, and down-select to one Phase II contract per topic. This is assuming that the proposals are sufficient in quality to fund this many. Proposals should concentrate on that research and development which will significantly contribute to proving the scientific and technical feasibility of the proposed effort, the successful completion of which is a prerequisite for further DoD support in Phase II. The measure of Phase I success includes technical performance toward the topic objectives and evaluations of the extent to which Phase II results would have the potential to yield a product or process of continuing importance to DoD and the private sector, in accordance with Section 4.3.

Subsequent Phase II awards will be made to firms on the basis of results from the Phase I effort and the scientific and technical merit of the Phase II proposal in addressing the goals and objectives described in the topic. Phase II awards will typically cover 2 to 5 person-years of effort over a period generally not to exceed 24 months (subject to negotiation). Phase II is the principal research and development effort and is expected to produce a well defined deliverable prototype or process. A more comprehensive proposal will be required for Phase II.

Under Phase III, the DoD may award non-SBIR funded follow-on contracts for products or processes, which meet the Component mission needs. This solicitation is designed, in part, to encourage the conversion of federally sponsored research and development innovation into private sector applications. The small business is expected to use non-federal capital to pursue private sector applications of the research and development.

This solicitation is for Phase I proposals only. Any proposal submitted under prior SBIR solicitations will not be considered under this solicitation; however, offerors who were not awarded a contract in response to a particular topic under prior SBIR solicitations are free to update or modify and submit the same or modified proposal if it is responsive to any of the topics listed in this section.

For Phase II, no separate solicitation will be issued and no unsolicited proposals will be accepted. Only those firms that were awarded Phase I contracts, and have successfully completed their Phase I efforts, will be invited to submit a Phase II proposal. Invitations to submit Phase II proposals will be released at or before the end of the Phase I period of performance. The decision to invite a Phase II proposal will be made based upon the success of the Phase I contract to meet the technical goals of the topic, as well as the overall merit based upon the criteria in section 4.3. DoD is not obligated to make any awards under Phase I, II, or III. DoD is not responsible for any money expended by the proposer before award of any contract. For specifics regarding the evaluation and award of Phase I or II contracts, please read the front section of this solicitation very carefully. Every Phase II proposal will be reviewed for overall merit based upon the criteria in section 4.3 of this solicitation, repeated below:

a. The soundness, technical merit, and innovation of the proposed approach and its incremental progress toward topic or subtopic solution.
b. The qualifications of the proposed principal/key investigators, supporting staff, and consultants. Qualifications include not only the ability to perform the research and development but also the ability to commercialize the results.
c. The potential for commercial (defense and private sector) application and the benefits expected to accrue from this commercialization.

In addition, the OSD SBIR Program has a Phase II Plus Program, which provides matching SBIR funds to expand an existing Phase II contract that attracts investment funds from a DoD acquisition program, a non-SBIR/non-STTR government program or Private sector investments. Phase II Plus allows for an existing Phase II OSD SBIR contract to be extended for up to one year per Phase II Plus application, to perform additional research and development. Phase II Plus matching funds will be provided on a one-for-one basis up to a maximum $500,000 of SBIR funds. All Phase II Plus awards are subject to acceptance, review, and selection of candidate projects, are subject to availability of funding, and successful negotiation and award of a Phase II Plus contract modification. The funds provided by the DoD acquisition program or a non-SBIR/non-STTR government program must be obligated on the OSD Phase II contract as a modification prior to or concurrent with the OSD SBIR funds. Private sector funds must be deemed an "outside investor" which may include such entities as another company, or an investor. It does not include the owners or family members, or affiliates of the small business (13 CFR 121.103).

The Fast Track provisions in section 4.0 of this solicitation apply as follows. Under the Fast Track policy, SBIR projects that attract matching cash from an outside investor for their Phase II effort have an opportunity to receive interim funding between Phases I and II, to be evaluated for Phase II under an expedited process, and to be selected for Phase II award provided they meet or exceed the technical thresholds and have met their Phase I technical goals, as discussed Section 4.5. Under the Fast Track Program, a company submits a Fast Track application, including statement of work and cost estimate, within 120 to 180 days of the award of a Phase I contract (see the Fast Track Application Form on www.dodsbir.net/submission). Also submitted at this time is a commitment of third party funding for Phase II. Subsequently, the company must submit its Phase I Final Report and its Phase II proposal no later than 210 days after the effective date of Phase I, and must certify, within 45 days of being selected for Phase II award, that all matching funds have been transferred to the company. For projects that qualify for the Fast Track (as discussed in Section 4.5), DoD will evaluate the Phase II proposals in an expedited manner in accordance with the above criteria, and may select these proposals for Phase II award provided: (1) they meet or exceed selection criteria (a) and (b) above and (2) the project has substantially met its Phase I technical goals (and assuming budgetary and other programmatic factors are met, as discussed in Section 4.1). Fast Track proposals, having attracted matching cash from an outside investor, presumptively meet criterion (c). However, selection and award of a Fast Track proposal is not mandated and DoD retains the discretion not to select or fund any Fast Track proposal.

Follow-On Funding

In addition to supporting scientific and engineering research and development, another important goal of the program is conversion of DoD-supported research and development into commercial (both Defense and Private Sector) products. Proposers are encouraged to obtain a contingent commitment for follow-on funding prior to Phase II where it is felt that the research and development has commercialization potential in either a Defense system or the private sector. Proposers who feel that their research and development have the potential to meet Defense system objectives or private sector market needs are encouraged to obtain either non-SBIR DoD follow-on funding or non-federal follow-on funding, for Phase III to pursue commercialization development. The commitment should be obtained during the course of Phase I performance, or early in the Phase II performance. This commitment may be contingent upon the DoD supported development meeting some specific technical objectives in Phase II which if met, would justify funding to pursue further development for commercial (either Defense related or private sector) purposes in Phase III. The recipient will be permitted to obtain commercial rights to any invention made in either Phase I or Phase II, subject to the patent policies stated elsewhere in this solicitation.

Contact with DoD

General informational questions pertaining to proposal instructions contained in this solicitation should be directed to the topic authors and point of contact identified in the topic description section. Proposals should be electronically submitted. Oral communications with DoD personnel regarding the technical content of this solicitation during the pre-solicitation phase are allowed, however, proposal evaluation is conducted only on the written submittal. Oral communications during the pre-solicitation period should be considered informal, and will not be factored into the selection for award of contracts. Oral communications subsequent to the pre-solicitation period, during the Phase I proposal preparation periods are prohibited for reasons of competitive fairness. Refer to the front section of the solicitation for the exact dates.

Proposal Submission

Proposals shall be submitted in response to a specific topic identified in the following topic description sections. The topics listed are the only topics for which proposals will be accepted. Scientific and technical information assistance may be requested by using the SBIR/STTR Interactive Technical Information System (SITIS).

It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Web site at http://www.dodsbir.net/submission. If you experience problems submitting your proposal, call the help desk (toll free) at 866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit of 25 pages. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The proposal submission Web site allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report. We **WILL NOT accept any proposals which are not submitted through the on-line submission site.** The submission site does not limit the overall file size for each electronic proposal, only the number of pages is limited. However, file uploads may take a great deal of time depending on your file size and your internet server connection speed. You are responsible for performing a virus check on each technical proposal file to be uploaded electronically. The detection of a virus on any submission may be cause for the rejection of the proposal. We will not accept e-mail submissions.

The following pages contain a summary of the technology focus area, which is followed by the topics.

Defense Health Program Biomedical Technology Focus Area

The Department of Defense is aggressively pursuing unified Force Health Protection and Deployment Health strategies to protect Service members and their families from health hazards associated with military service. Toward that end, DoD is undertaking technology development programs that save lives and promote healthy individuals, units and communities while improving both force morale and warfighting capabilities.

The operational force is exposed to health threats throughout the operational continuum, from CONUS fixed facilities (garrison, base, ashore) through deployment, employment, and redeployment. DoD is developing policy and procedures to assess occupational and environmental health threats for all locations.

When Force Health Protection capabilities are fully implemented, commanders will have a more complete view of potential health threats. Integration of assessments from health databases and other assessments from intelligence (e.g., about land mines, directed enemy fire, fratricide) and safety (e.g., about injuries, vehicle accidents, explosives, aviation mishaps) will provide a framework for identifying future medical technology capabilities necessary for Force Health Protection.

Ensuring the health of the force encompasses several key capabilities:

- To mobilize, deploy and sustain medical and health support for any operation requiring military services;
- To maintain and project the continuum of healthcare resources required to provide for the health of the force;
- To operate in conjunction with beneficiary healthcare; and
- To develop training systems which provide realistic rehearsal of emergency medical and surgical procedures and unit-level medical operations.
- These capabilities comprise an integrated and focused approach to protect and sustain DoD's most important resource—its Service members and their families—throughout the entire length of service commitment.

The Office of the Secretary of Defense believes that the small-business community can be effective in developing new technology-based approaches to needs in force health protection. Three broad capability areas of particular interest are tools and techniques for near real-time surveillance of the health threats and health status of the Force, for epidemiology research, and for delivery of health education and training. These are described in more detail below:

- Health Surveillance Planning and Decision Support Tools: Tailorable and targeted software applications that are integrated into the Military Health System's backbone of installed information systems are the essential enabling technology for surveillance. Applications in the areas of decision support tools, data and knowledge management, information visualization technologies including geospatial tools, and artificial intelligence-based appliqués for essential analyses are needed. It is expected that the applications would produce a comprehensive system of risk based assessments, predictions, and courses-of-action utilizing epidemiological, intelligence, environmental exposure, and health information concerning deployed forces. The applications should also allow for predictive modeling of medical readiness scaleable from individuals to the aggregated Force, given such data streams as reported real and somatic symptoms.

- New Methods to Monitor Health Status and Clinical Laboratory Data: Monitoring of health status during deployments is necessary to determine etiologic factors of deployment related health change. Data and information analysis tools are needed to collect and harmonize disparate data and information sources and to provide health status surveillance pre- or post-injury to medical information consumers within and outside of military medical channels. Health monitoring should be for a limited set of indicators, and should yield an unambiguous interpretation of health status. Projects are required to have a strong biological basis and be sensitive to changes in health status based on either real-time measurements from warfighters in an operational environment, clinical laboratory data sources, and/or recorded in-patient or out-patient or trauma registry data.

- Medical Training and Learning Tools: Developing and maintaining skills among the personnel of the Military Health System is an important aspect of deployment health. Advanced distributed learning, simulation-based training and other computer-based training technology should enable all health-care personnel to plan, respond and manage the future medical missions, and should assist medical professionals to maintain clinical knowledge and skills. Tools that can be extended to use by the general military population for proactive preventive medicine are desirable. Tools should be based on existing medical and allied health knowledge, should be universally accessible, should allow for unlimited practice, and should be SCORM-compliant in content and in delivery modalities.

OSD SBIR 093 Topic Index

The Defense Health Program Biomedical Technology topics are:

OSD SBIR 093 Topic Descriptions

OSD09-H06 TITLE: Neuromonitoring of Traumatic Brain/blast Injury

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Design and build an inexpensive, portable brain monitor/alarm for deployment on the battlefield, for use during transport of wounded soldiers, and for use in the neurosurgery ICU. The non-invasive device will monitor brain function continuously while unattended to detect and alert medical personnel of developing pathologic brain conditions such as edema, vasospasm, and increased intracranial pressure, which can cause secondary brain damage. The monitor should detect changes in cerebral blood flow (CBF) autoregulation (AR) (Strandgaard and Paulson, 1984), and activate an alarm when CBF AR has reached its lower limit and when failure of neuronal synaptic transmission occurs as a consequence of severe CBF decrease (Symon et al, 1986).

DESCRIPTION: The brain monitor will apply existing technology: EEG and Rheoencephalography (REG) (Moskalenko, 1980; Jenkner, 1986; Anonymous 1997; Grimnes and Martinsen, 2008). The brain monitor will 1) detect the lower limit of cerebral blood flow autoregulation (Bodo et al -1, 2005; 2007; Czosnyka et al, 1997; Anonymous 2; and 2) detect failure of neuronal synaptic transmission (defined as a 2 second isoelectric EEG period (Prior, 1973, Bodo et al 2001). The brain monitor will have sufficient memory (minimum 80 GB) to store both the EEG and REG analog signals during transport of wounded soldiers and in the neurosurgery ICU. These records can later be stored and connected to the DoD computer-based electronic health record (CHCS II, AHLTA).

PHASE I: Develop overall system design that includes specification of REG and EEG amplifiers, signal processing, data storage, monitoring, network connections.

PHASE II: Develop and demonstrate a prototype system in animal and human studies. Conduct testing to prove feasibility over extended operating conditions.

PHASE III: This system could be used in broad range of military and civilian applications where traumatic brain/blast injured patients needed to observe during transportation and neurosurgery ICU monitoring.

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KEYWORDS: CBF autoregulation, ICP, vasospasm, hypoxia, ischemia, edema, neuro-monitoring, EEG, REG

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OSD09-H07 TITLE: Evidence-Based Evaluation Process for Traumatic Brain Injuries and Co-morbid Psychological Disorders in Service Members

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To develop a user-friendly, empirically-based neuropsychological screening tool to be used by first responders. This tool will quickly and accurately identify service members who show probable impairments from combat-related experiences. In Phase II, an outcome prediction score will determine the need for further evaluation. Service members identified by prediction scores will be followed with longitudinal studies to determine risk factors associated with neurodegenerative disorders.

DESCRIPTION: If TBI is the signature injury of Operations Iraqi and Enduring Freedom (OIF/OEF), then PTSD and depression are the psychological correlates, each significantly contributing to life altering events or consequences for the service members, their families, and ultimately the community. Mild traumatic brain injury is strongly associated with emotional and physical health problems, of which PTSD and depression are important mediators.1 Approximately 19.5% of service members reported experiencing a probable TBI during deployment and 18.5% of all returning service members meet criteria for either PTSD or depression.2 There is a significant overlap between of military members who have experienced and/or witnessed a life threatening event and sustained a blast or other traumatic head injury. This overlap between traumatic brain injuries and co-morbid psychological disorders (i.e. PTSD, depression) in military service members requires further investigation.3, 4

The likelihood of having repeated deployments and cumulative mental and physical injuries are becoming more prevalent with the increasing number of multiple deployments. In addition, undiagnosed and/or untreated events occur, resulting in military members returning to the field and experiencing multiple blasts/ traumatic exposures. This repetitive and cumulative exposure, without appropriate time for rest and reset, has resulted in an overlap of psychomorphic conditions that are evidenced by emotional and neurocognitive changes.5

When able to rest, many military members have reported sleep pattern disturbances. These disturbances, often attributed to the combat setting or emotional disorders, may have a much deeper structural etiology in the TBI patient. A recent study discovered that individuals with closed head injuries had a higher incidence of sleep-wake cycle disturbances, resulting in longer stays in rehabilitation facilities, and additional emotional disturbances. These sleep cycle disturbances may serve as a marker for more severe injury and poorer outcomes.6

The awardee will assess the co-occurrence of these neurocognitive and emotional events, determine the problems and associated conditions, examine the long term implications and evaluate diagnostic instruments in order to distinguish who is most at risk for becoming impaired. This could ultimately aid in the determination of fitness for military duty and battle readiness. In addition, with more than 1.4 million people sustaining a TBI in the United States each year, the need for greater understanding of these injuries is evident in the civilian population as well.7

Currently, the standard of practice in the field has been to administer the Military Acute Concussion Evaluation (MACE), followed by further evaluation at the Battalion Aid Station (BAS). The MACE incorporates the Sports Concussion Assessment, therefore it is notable that most sports injuries include a single uncomplicated event that typically recovers within a week of injury, unlike the battlefield injuries noted above.8 Additionally, while this measure may have the sensitivity to detect severe brain injuries, some cases of mild brain injury may be missed; and this assessment does not include mental health measures which may identify psychological or emotional sequelae. Furthermore, validation of the MACE has not yet occurred.9

To date, there appears to be a large number of false negatives with current standard evaluative processes in the field. This results in delayed identification of patients who have been injured both medically and psychologically. Since most recovery of brain functioning occurs within the first 12 months, identifying these individual quickly and making sure they receive the proper evaluation and treatment in a timely manner is critical. There appears to be a need for a screening tool that addresses these needs and facilitates the triage process.

PERFORMANCE OBJECTIVES:

(1) Develop an evidence-based screening tool that is sensitive and specific to neurocognitive and emotional changes often seen in service personnel who have been exposed to blasts and/or closed head injuries. Results from this screening tool yield a predictability score, which signals whether more extensive evaluation is needed. The screening tool can be administered by paraprofessionals in the field who often serve as first-responders. This tool will be comprised of several already existent and well-researched neuropsychological measures. The neuropsychological tests chosen for this screening tool have been shown to be the most sensitive and specific indicators of both traumatic brain injuries related to over-pressurization (i.e., blast injuries) as well the emotional sequelae often associated with combat-related experiences.

(2) Once this brief screening tool is completed, an outcome prediction score is derived, which will determine if further and more thorough evaluations are warranted.

(3) Individuals obtaining scores above a preset cutoff will then be evaluated more extensively. Individuals who meet the criteria for clinical diagnoses, based on his /her level of impairment, will then be followed through longitudinal studies. These studies will examine rates of neurodegenerative processes, effects of sleep disorders and/or recovery rates for concurrent emotional disorders.

PHASE I: In Phase I, the awardee will investigate the feasibility of obtaining de-identified patient data to build an empirically-derived screening tool. This screening tool will be a result of statistical analyses of several standardized neuropsychological and psychological test measures. This database will contain multiple data points which aid in the identification of appropriate test instruments, and then be used to validate the instruments with the identified patient population. Review of the existing literature regarding the use of these test measures/instruments and their predictive power, thereby allowing for the identification of the factors influencing the functional status of soldiers returning from deployments to OIF and OEF will occur during this phase. This phase also includes the preparation of plans and protocols for any required human testing, as well as seeking local and Army regulatory approvals for potential Phase II work. (Any Phase I animal or human subject research is highly discouraged unless existing protocols are already approved by local boards and can be quickly prepared for second-level review by the U.S. Army Medical Research and Materiel Command Office of Research Protections.)

The strengths of this screening tool should include:
• Based on standardized tests
• Test-retest measures can be used for longitudinal studies
• Empirically-based measures through multiple regression
• Brief, inexpensive, and sensitive
• First responders can administer and make recommendations based on prediction score (i.e., scores above cutoff warrants further evaluation)
• Extensive assessment training is not required to administer the screening tool
• Baseline measures can be obtained immediately after an injury and/or blast and provides baseline data for other healthcare professionals to monitor changes in neurocognitive and emotional functioning.
• Statistics to account for practice effects
• Aspire to establish validity indexes/scales to establish response style. For example, individuals may minimize, exaggerate, or feign underlying symptoms.

The results from Phase I will be used to improve the sensitivity, specificity and predictability of standard psychological and neuropsychological test results. This will enable more accurate diagnosis of psychological disorders and traumatic brain injury thus allowing more informed judgments about fitness for duty and battle readiness.

PHASE II: In Phase II the awardee will conduct a retrospective study using a data pool, of at least 400 subjects, in order to identify the main areas of impairment that are observed in military service members exposed to blast wave injuries. Regression analyses and/or principle parts analyses should serve as the statistical measures. The data should include neuropsychological and psychological measures as well as multiple clinical data points including sleep/wake cycle disturbances, perceptual changes, presence and frequency of headaches, changes in energy level, changes in speed of thinking, medical history, psychological treatment history, etc. Other factors include MMPI-2 code types, the ANAM scores, measures of verbal/visual memory, attention/concentration, executive functioning, perceptual and processing speed, etc.

PHASE III: A more predictive screening tool and standardized evaluation process will have widespread implications and applications for the care and treatment of neurologic and psychological patients in both military and civilian sectors. These tools will enable identification of domains of neurocognitive and psychological impairment. Long-term consequences of blast/PTSD and other co-morbid conditions will be examined to determine recovery patterns among injured personnel, including rates of recovery and related abilities to return to duty (including fitness for duty and combat readiness). Additional applications of this data include: Develop therapeutic models to facilitate the recovery process and expected outcomes of such interventions; Identify more effective rehabilitation interventions and the efficacy of such interventions in these conditions and explain how the expected brain dysfunction from a blast injury differ from general head trauma. The screening tool will ultimately lead to the development of a standard of care, diagnostic battery that is not only effective, but cost efficient, to enable quicker and more accurate diagnosis and a treatment algorithm which should allow for better care of not only the war fighter, but the civilian trauma population. Based on the data from Phase I and II, sleep studies may be warranted to evaluate sleep/wake cycles in persons with either traumatic brain injury and/or psychological disorders (i.e., PTSD & Depression); therefore the awardee should have the capability of performing these studies as well.

Further questions that may be answered from this data include:

- Does concurrent treatment of these disorders lead to better outcome than sequential treatment?
- Does the type of treatment have an effect on recovery?
- Is the stigma of treatment for psychological conditions lessened because of the TBI diagnoses?
- Are rates of degenerative nervous system diseases (Alzheimer's, Parkinson's, Amyotrophic Lateral Sclerosis) in persons with blast-related TBIs comparable to other TBIs from better researched areas of injury (e.g., motor vehicle accidents).

This study could lead to other ancillary projects that are treatment focused to include therapy, medications (drug trials) and genetic studies, etc.

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KEYWORDS: Depression, Post-Traumatic Stress Disorder, Traumatic Brain Injury, Concussion, Mental Health, Dual-Diagnosis, Psychiatric, Outcome, Diagnostic Instruments.

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OSD09-H08 TITLE: Early Detection of Mild Traumatic Brain Injury

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: The objective of this effort is to develop a new innovative method(s) to quantify the presence of sleep-wake disorder, poor sleep quality and other sleep abnormalities that is correlated to Mild Traumatic Brain Injury sustained in combat by soldiers who have recently experienced head trauma.

DESCRIPTION: In January 2008, the Department of Defense reported a total of 5,503 soldiers currently suffering with traumatic brain injuries (1). Mild Traumatic Brain Injury is the most common kind of combat injury frequently leading to cognitive deficits in attention, speed of information processing, and working and long-term memory performance. As many as 30% of patients with Mild Traumatic Brain Injury show neurological symptoms (e.g. headaches, dizziness, and irritability, and neurocognitive deficits) long after the initial head trauma. Early detection and screening of positive Mild Traumatic Brain Injury status is difficult in the immediate post-trauma period and new and efficient screening methods of assessment are needed. It is known that Mild Traumatic Brain Injury is strongly associated with sleep-wake disorder characterized by excessive daytime sleepiness, hypersomnia and fatigue. Recent research in non-military populations has shown that sleep quality and resulting sleep deprivation, may be responsible for these symptoms. Further, sleep disorders disrupt sleep consolidation of recent learning and resulting sleep deprivation is associated with impaired cognitive functioning.

This topic is searching for the development of new innovative methods to quantify the presence of sleep-wake disorder, poor sleep quality and other sleep abnormalities that is correlated with mild traumatic brain disorder in combat soldiers who have recently experienced head trauma. This devise will be using different integrations and will be more sensitive than the one already approved by the FDA which cannot detect early enough the subtle change in sleep awake disorder that are seen in mild traumatic brain injuries. Such devices or methods would allow the practitioner or military medical personnel to characterize and identify patient status or risk of Mild Traumatic Brain Injury in the early stages before triage.

Sleep disturbances can compromise the rehabilitation process of our Veterans and Military as well as affect their ability to return to work due to dysfunctional cognition from lack of sleep (2). A successful device could lead to a diagnosis and subsequent treatment of Mild Traumatic Brain Injury and contribute to corporeal and cognitive rehabilitation of these patients.

PHASE I: Phase I work shall include proof-of-concept data that shows that the method(s) to quantify the presence of sleep-wake disorder, poor sleep quality and other sleep abnormalities will be able to provide data points relating to the identification of Mild Traumatic Brain Injury. During this phase, algorithms and parameters will be defined and proved. The results should include a proof-of-feasibility demonstration of primary concepts.

PHASE II: The researcher shall design, develop, test, and demonstrate a prototype tool that implements the Phase I methodology to detect Mild Traumatic Brain Injury. The researcher shall describe in detail the plan for the Phase III effort.

PHASE III: Refine the methodology to detect Mild Traumatic Brain Injury from Phase II and provide validation of results. Military application: The desired method/device will allow military practitioners to assess Mild Traumatic Brain Injury. Commercial application: Health professionals' world-wide could utilize this product to assess Mild Traumatic Brain Injury such as environmental disasters, automobile accidents, and sports injuries.

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KEYWORDS: Mild traumatic brain injury, sleep loss, sleep-wake, algorithm, impaired cognitive function

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OSD09-H09 TITLE: Actively Compliant Parallel End-Effector Mechanism for Medical Interventions

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Design and develop a six degree-of-freedom parallel end-effector mechanism that can be mounted on the end of a medium-sized robot manipulator for compliance-based medical imaging and surgical interventions.

DESCRIPTION: The military is currently developing several robotic systems for both teleoperated and autonomous interventions for use in the operating room of the future (Cleary et al, 2004). Intuitive Surgical’s da Vinci® surgical robot broke ground in 1998 by performing the first tele-robotic surgery to repair a heart valve (Guthart & Salisbury, 2000), and Accuray’s CyberKnife radiotherapy robot began treating head, neck and upper spine tumors in 1999 by combining image guidance with a robotically-directed radiation beam (Adler et al., 1997). Ultrasound represents one of the most promising new technologies for use both on and off the battlefield. High-resolution ultrasound imaging can be used to detect internal bleeding (Alvarado et al, 2008) and bone fractures (Lo et al, 2008), and an ultrasonic welding device is now being applied as an alternative to manual suturing (Garcia, 2007). During these procedures, it is typically required that a specified level of force be applied on the patient, which is made particularly difficult because of the compliance of soft skin tissue and involuntary movements due to respiration. It is extremely difficult for a serial-link manipulator to respond quickly enough to accommodate this motion due to high inertia and inaccuracies caused by low stiffness at the tool point. Ultrasonic probes have been mounted and demonstrated on parallel manipulator devices (Ding et al, 2008), but the range of motion is very limited. Alternatively, serial-parallel robot architectures can be implemented in which the serial robot moves the probe into close proximity of the patient, while a parallel mechanism end-effector maintains constant force contact of the probe using minute adjustments (Carbone and Ceccarelli, 2005). In addition to providing increased accuracy and bandwidth, a robotic end-effector mechanism will also yield increase the level of safety through active compliance. Several technologies are potential candidates for this research topic, although dc electric motor-based technologies are preferred. Approaches that could potentially be used include using linear joints such as lead-screws or pistons currently employed in Stewart platforms or rotary joints to drive differential gears to cause multi-axis movement of linkages. In addition to novel end-effector design, research challenges inherent in this topic include actuator devices, colocated sensing, mechanical efficiency, miniaturization, ruggedization, local processing, communication, and packaging. For example, colocated sensing represents a particular challenge due to the close proximity of the actuators and rugged environment in which the device must operate which may be inhospitable to optical encoders typically employed in these applications.

PHASE I: Conceptualize and design a prototype parallel end-effector mechanism that meets the following requirements: mass < 5 Kg, force > 50 N, torque > 5 N-m/rad, force resolution < 0.5 N, position accuracy < 2 mm, position repeability < 0.5 mm, stiffness > 10000 N/m, range of motion 5 cm translation and 30 deg rotation, and diameter < 15 cm x height < 15 cm. Develop a research plan for Phase II.

PHASE II: Develop, integrate, and test a prototype parallel end-effector mechanism that meets the Phase I requirements. Design and implement a controller that can achieve active compliance of less than 2 N/cm up to 10 Hz bandwidth. Demonstrate this system on a serial-link manipulator used in a surgical suite such as a Mitsubishi PA-10 manipulator. Develop a commercialization plan for Phase III.

PHASE III: Assist the Army in transitioning and implementing the parallel end-effector mechanism to a commercial robot application in a surgical suite. Develop and market a commercial version of the end-effector for use in hospitals with trauma units.

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KEYWORDS: robot, sensors, parallel mechanism, end-effector, stewart platform, remote triage, ultrasound, combat casualty care

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OSD09-H10 TITLE: Natural Polymers for Cranio-facial Tissue Engineering

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop resorbable natural polymer matrices that guide biological repair and promote healing of cranio-facial injuries. The biomaterial should have broad biocompatibility to repair and revascularize damaged tissue seen in traumatic injuries (i.e. bone, muscle cartilage and skin). Examples of natural polymers that have been previously studied for use in tissue engineering include: collagen and alginate.

DESCRIPTION:
In recent military conflicts involving American military personnel, such as Operation Desert Shield/Storm and Operation Iraqi Freedom the majority of injuries (60%) that required hospitalization and transport from theater involved injuries to the extremities (1-3). It can be assumed that these injuries involve losing large portions of muscle, bone and/or missing skin. Currently, the clinical treatment of extremity and cranio-facial trauma confront the challenge of poor regenerative potential and inferior function after repair, which can lead to extended rehabilitation, multiple surgical procedures and possibly permanent disabilities. Recent advances in tissue engineering indicate that adult stem cells and biomaterials may provide a source of regenerative tissue that may be clinically useful for de novo formation of muscle, bone and skin lost to trauma (4,5).

There is a need to develop new natural material matrices for biomedical research and tissue engineering applications. Such materials must be biodegradable, easily formulated and mimic the mechanical attributes of the injured tissue, produced in various formulations (e.g. gel, sheet) and porosity, as well as easily isolated and manufactured in large quantities.

PHASE I: Identify a natural polymer or family of polymers the can be used to repair or replace portions of or whole tissues (i.e. bone, muscle, skin). The system must replicate the structural and mechanical properties of each tissue and produce functional equivalent tissue in vitro, so the engineered product can replace, restore or improve tissue/organ function. The material should be non-toxic and encourage cell attachment, proliferation and differentiation.

PHASE II: Test the efficacy of the materials in vivo and determine the preferred embodiment for each tissue type in animal experimental models. The safety (i.e. toxicity and immunogenicity) of each combination of biomaterial in vivo should be determined and necessary redesign based on performance evaluated.

PHASE III: The most promising biomaterial formulations will be analyzed in additional in vitro assay and in vivo tested in a more realistic large animal model. The overall program will provide natural biomaterials that can be used for reconstructive surgery and be effectively commercialized for both civilian and military trauma care.

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KEYWORDS: Natural Biomaterials, Tissue engineering, Biomaterials, Cranio-facial/extremity injury

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OSD09-H11 TITLE: Bioreactors for Tissue Reconstruction

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop a device capable of in vitro culture of stem cells into three-dimensional tissues that can be used for in vivo tissue engineering experiments. The device should be broadly applicable to develop numerous tissue types that can then be used to repair damaged tissue due to traumatic injuries.

DESCRIPTION: In recent military conflicts involving American military personnel, such as Operation Desert Shield/Storm and Operation Iraqi Freedom the majority of injuries (85%) that required hospitalization and transport from theater involved injuries to the extremities and craniofacial region(1-3). Many of these injuries involve losing large portions of muscle, bone and/or missing skin. Currently, the clinical treatment of extremity and cranio-facial trauma confront the challenge of poor regenerative potential and inferior function after repair, which can lead to extended rehabilitation, multiple surgical procedures and possibly permanent disabilities. Recent advances in tissue engineering indicate that adult stem cells and biomaterials may provide a source of regenerative tissue that may be clinically useful for de novo formation of muscle, bone and skin lost to trauma (4,5).

There is a need to develop new devices for tissue engineering applications. Such devices must be flexible (i.e., modular components), autoclavable (or disposable) and easily adaptable to function with pre-existing laboratory equipment.

PHASE I: Identify a device or technology that can be used to repair or replace portions of, or whole tissues (i.e. bone, functional skeletal muscle, and skin). The device should provide a biomimetic environment to fabricate tissues using a wide variety of biomaterial and stem cell combinations. The system must replicate the structural and mechanical properties of each tissue and produce functional equivalent tissue in vitro, so the engineered product can replace, restore or improve tissue/organ function. The size of engineered tissue constructs is almost always limited by diffusion; therefore, this bioreactor must promote vasculogenesis and bring the field closer to the goal of implantable, functional tissue.

PHASE II: Test the efficacy of device(s) and determine the preferred embodiment that will be fabricated and tested in vitro and in animal experimental models. The device and necessary redesign based on performance will be evaluated.

Phase III: The most promising device will be analyzed in additional in vitro and in vivo testing in a more realistic large animal model. The overall program will provide alternatives to standard reconstructive surgery and be effectively commercialized for both civilian and military trauma care.

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KEYWORDS: Bioreactor, Tissue engineering, Biomaterials, Cranio-facial/extremity injury

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OSD09-H12 TITLE: Application of Semantic Web Technologies to Alert Providers Regarding Poly-Pharmacy Issues in Traumatic Brain Injury (TBI) and/or Post-Traumatic Stress Disorder (PTSD) Military Patients

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop and demonstrate semantic web technologies to alert providers about poly-pharmacy issues with active duty patients diagnosed with Traumatic Brain Injury (TBI) and/or Post-Traumatic Stress Disorder (PTSD). As a secondary objective, work to enhance pharmacovigilance and prevent drug-related near miss, adverse drug event, and sentinel event reporting for all patients, and better integrate Department of Defense (DOD) and Food and Drug Administration (FDA) systems involved in these efforts. By Phase II of the project, this effort will require the vendor to build a working prototype to demonstrate how semantic web technologies can mediate disparate disease classification, evaluation and management, and drug adverse event reporting terminologies present in several military and civilian health management information systems, and output meaningful data for improved outcomes management of TBI and PTSD patients.

DESCRIPTION: Recent news reports, notably those involving the deaths of Army Sergeants Gerald Cassidy and Robert Nichols, have emphasized the fact that TBI and PTSD patients are receiving many medications to treat their conditions. Such a situation increases the possibility of adverse drug events, which can lead to the unnecessary illness, or in these cases, deaths of patients. In Nichols' case, eleven drugs were found in his body at autopsy. It is highly likely that other TBI and PTSD patients are at risk from complex drug interactions or over-dosing a combination of drugs. The situation becomes even more complicated when multiple drugs are prescribed and the patient is drinking alcohol or taking over the counter drugs and supplements. Increases in risk-taking behavior and/or physical and emotional pain related to TBI and PTSD can also result in taking drugs of abuse which again adds to the complexity of the issue.

There has been little research directly addressing the problem of poly-drug treatment of TBI and PTSD patients. The Military Health System does recognize that current information technology management systems to promote pharmacovigilance and prevent adverse drug events, near misses, and sentinel events suffer from the issue of disparate disease classification, evaluation and management, and differing drug adverse event reporting terminologies.

The proposed SBIR will build upon the current, very early state of research in use of semantic web technologies in healthcare. Conducting pharmacovigilance and post-marketing drug surveillance often requires combining disparate sources of data which are based on disparate medical concepts and terminologies. It is often difficult to mediate differences in medical concepts terminologies to make sense out of the data. Using semantic web technologies can help clinicians and researchers understand differences in medical concepts and terminologies.

For example, electronic health records contain medical terminologies which represent knowledge of disease classifications and evaluation and management of the patients, such as Medicomp MEDCIN, ICD-9, ICD-10, CPT-4, LOINC, SNOMED, and others. On the other hand, adverse event terminologies are largely based on MedDRA, the Medical Dictionary for Regulatory Activities, although other reporting taxonomies have also been developed and are in use. MedDRA is a pragmatic, medically valid terminology with an emphasis on ease of use for data entry, retrieval, analysis, and display, as well as a suitable balance between sensitivity and specificity within the regulatory environment. MedDRA terminology applies to all phases of drug development, excluding animal toxicology. It also applies to the health effects and malfunction of devices. The size and complexity of MedDRA terminology carries the risk that different users may select differing sets of terms while trying to retrieve cases relative to the same drug safety problem. It has also been stressed that the active participation of drug regulatory authorities in the preparation of search queries is essential for their subsequent acceptance of search results and that there is a need to agree upon how the search results should be presented using a specially designed template.

One area of immediate interest to the Military Health System (MHS) is how to map ICD-9 and ICD-10 to MedDRA. This might be accomplished using UMLS or the other code sets contained within, such as SNOMED 2, or through use of the existing 3M HDD product in the Armed Forces Health Longitudinal Technology Application (AHLTA).

Another area of potential interest is how to automatically map institutional-specific terms and codes that are developed in electronic medical record systems at military treatment facilities (MTFs), such as in CHCS and AHLTA. Users need a way to track when theses terms and codes came into use at the institution, and when they are entered into the system's central health data dictionary (HDD), which is a 3M commercial product. Once changes are made in one system, they need to automatically update the other systems involved.

The same is true for Logical Observation Identifiers Names and Codes (LOINC) codes for labs, and cohort specific data such as smoking, body mass index (BMI), radiology, and other cohort specific data. 3M NCID codes may be able to address the mapping of LOINC, ICD-9, ICD-10, and Drug Codes.

Another reported area of concern is that the Department of Veterans Affairs uses a different drug dictionary than most others; additional terminology mediation may be necessary here.

The research should determine if it is feasible to leverage the 3M Health Data Dictionary, which is currently used to normalize lab results coming from MHS CHCS to the MHS AHLTA system using a unique Numeric Concept Identifier (NCID), and contains multiple cross-mapping of tools, for use in other systems which support pharmacovigilance.

This option needs to be evaluated along with using other meta-thesauri, such as the Unified Medical Language Service (UMLS), or other medical ontologies, such as LinkBase from Language and Computing.

The research should also examine whether these knowledge representation schemes, meta-thesauri, and/or ontologies are compatible with the RDF and OWL technologies employed by the Semantic Web.

This research may also explore ways of semantically exchanging data with the FDA Sentinel Network concept, if the FDA is willing to commit resources to this SBIR. Through Sentinel, FDA intends to capitalize on emerging technologies and new sources of data. Its goal is to be able to mine claims data and electronic health records to help ensure that medical products are optimally used in post-marketing settings.

The research may also determine how semantic web technology may be best applied to exchange of Military Health System data with the JANUS Clinical Data Repository. This may or may not involve extended use of the 3M HDD. As a matter of background, JANUS is a standards-based clinical data repository that utilizes the open source data model, Janus. This repository provides a data collection and analysis warehouse for clinical trial data submitted for protocols (what was supposed to happen) as well as clinical outcomes data (what did happen - events, interventions, etc.). When implemented, Janus will enhance the clinical trial process by allowing the viewing of the data through reviewer-centric tools; cross-study analyses; cross-application analyses; audit capabilities; and enhanced communication of conclusions. It will contain patient information as well as intellectual property information of the sponsor agencies that have supplied the investigational agents. The JANUS vision is to incorporate SAEs (ARES type data), so that could bring the whole lifecycle of any drugs (pre-market, post-market) safety data together in future, and provide a better understanding for any drugs safety evolution. Janus uses NCI"s EVS (enterprise vocabulary service) which contains a lots common terminology that is also available in UMLS.

NDC (National Drug Code System) is the common coding system used for clinical drug trials and for post-marketing drug surveillance drugs. NDC is not included in UMLS, and thus not part of the Janus Environment.

Given this barrier to semantic interoperability, as one idea, this SBIR might create a drug ontology engine that:

a. maps between NDC to the drug naming schema used in Janus (SNOMED); this would be essential to bridge the huge gap between pre-market and post market drug safety analysis in FDA

b. unifies NDC (and other clinical use drug code, like VA’s drug file) with drug terminology used in clinical research world provide the tool to facilitate DoD commitment to take part in the national sentinel network: seamlessly integrate MHS clinical data to national research environment

c. strengthens DOD‘s ability to utilize multiple data source to conduct post-market pharmacovigilance activities to make better informed decisions to guild our drug use safety

d. enhances data analysis capabilities through building enriched drug entity attributes/characteristics.

PHASE I: In Phase I, the SBIR awardee will meet with MHS to refine the problem and research objectives. The awardee will meet with other interested government agencies already working with DoD, such as FDA and VHA, to the extent that they are available and interested.

The awardee will leverage past research involving the application of semantic web technologies to healthcare surveillance, pharmacovigilance, post-marketing drug studies, and drug-related near miss/adverse/sentinel event reporting, with a focus on TBI and PTSD patients.

The awardee will also conduct a survey of semantic web tools which currently exist, such as those developed by Dr. Parsa Mirhaji at the University of Texas, Health Science Center, Houston, and others, such as those licensed by Apelon, Language and Computing, and 3M, as well as other open source tools. The vendor should conduct a test of the accuracy of such tools in translating various code sets to MEDDRA and vice-versa.

In addition the government is interested in applying semantic and ontological-based Natural Language Processing technologies to free text in radiology and pathology reports to output codes.

The awardee will assess architectural alternatives for applying semantic web technologies to mediate differences in terminologies between MHS and external systems which collect or feed data in these domains. Which systems would be involved would be determined in an analysis of alternatives. The likely MHS systems involved might include AHLTA, CHCS, the MHS Clinical Data Mart (CDM), the MHS M2 Business Repository, or the MHS Patient Safety Reporting System, or others, including those in the FDA. (The research will not focus on record level error reports as found in USP MEDMARX).

Emphasis will be on outlining a systems, operational, and technical approach to achieving semantic interoperability for data exchange between MHS systems, and/or between MHS and FDA systems, such as JANUS, with a focus on how terminology differences can be mediated. Whether JANUS will be involved is dependent upon resources available at the FDA and CDC. The focus will remain on mediating terminology in the TBI and PTSD domains. Phase I will also determine the metrics by which success will be judged. Likely metrics would measure the degree to which semantic web technologies can provide automated, accurate mappings of terminologies, and/or improved understanding of disparate data by researchers and clinicians, with a focus on the TBI and PTSD domains.

PHASE II: In Phase II, the SBIR awardee will build a prototype system(s) demonstrating how semantic web technologies can be applied to achieve exchange of data with semantic interoperability, based on the architecture defined in Phase I, and focusing on the TBI and PTSD domains. The prototype system(s) should show exchange of data between MHS systems involved with pharmacovigilance, post-marketing drug surveillance, and/or drug adverse event reporting, or between MHS system(s) in these domains and the NIH/FDA JANUS clinical data repository. The systems involved would be determined in Phase I.

PHASE III: In Phase III, the SBIR vendor would transition the prototype system(s) to production quality system(s), or exchange of data between existing systems. This would involve the complete design, development, testing, deployment, and sustainment of the system, under the oversight of the TRICARE Management Activity Joint Medical Information Systems Office (JMISO) and Military Health System Chief Information Officer, through an IT Program Office, such as Executive Information/Decision Support. Functional clinical champions would be designated at the TRICARE Management Activity, and would likely include the DoD Pharmacy Program and Army Surgeon General’s Office. The system will also be refined to function with civilian based electronic health records systems of potential customers.

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KEYWORDS: Semantic Web; Traumatic Brain Injury (TBI); Post-Traumatic Stress Disorder, Healthcare (PTSD); Pharmacovigilance; Post-Marketing Drug Surveillance; Near Miss, Adverse Event, and Sentinel Event Reporting; U.S. Food and Drug Administration (FDA) Sentinel Initiative; Ontologies; Drug Safety; Patient Safety, JANUS Clinical Data Repository, AHLTA, CHCS, Military Health System (MHS)

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OSD09-H13 TITLE: Aeromedical Stabilization and Evacuation of Traumatic Brain and Spine Injuries: A Novel System for Patient Transport

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To develop a lightweight, component-based, “litter agnostic” system that will provide cervical spinal traction, and thoracic/lumbar splinting as needed, and will include a pressure and shock absorbing mattress system or pronating system to improve stabilization and transport of subjects with spinal cord injuries (SCI), traumatic brain injury (TBI) and polytrauma during fixed wing and rotary medical evacuations. in order to limit motion including torsion from turbulence, erratic forces, gravitational and vibratory effects.

DESCRIPTION: Traumatic brain injuries are often associated with spinal injuries. Air transport of these injured patients is critical to obtain life and function-saving treatment in a medical facility with neurosurgical capabilities. Immobilization of traumatically injured patients during transport is essential in reducing risk of further spinal injuries. Some co-morbidities associated with spinal cord injury patients are secondary to improper immobilization and include pressure sores and destabilization of fractures. Forces that are exerted on patients evacuated in either fixed wind or rotary aircraft include torsion from turbulence, gravitational and vibratory effects from the aircraft. Additionally, military pilots may have to resort to rapid ascent/descent as well as erratic maneuvers to avoid hostile fire. These forces require unique stabilization techniques to prevent additional injury and improve transport for the injured warfighter. In the past, the Stryker frame was used to rotate patients to limit pressure sores. As the military phases out of this system, we believe that technology has advanced to the point where bedding systems can be used without the need for rotating the patient (and without the size and space required for that).

This topic proposes that the awardee will assess the forces acting upon military trauma patients and develop/refine methods to develop an immobilization device that permits victims of head and spinal column trauma to be firmly supported for transportation. The technology should be capable of head, cervical, thoracic, and lumbar support and cervical traction as needed. The device can be created by either moving new research into development or integrating existing technologies to develop the desired product. We require a portable, lightweight system that can be easily carried into field hospitals and used to move patients to the flight line and through air evacuation. Weight and safety considerations imposed by the aircraft must also be taken into account by the awardee (e.g. must conform to size and securing requirements for standard NATO litters). It must be practical to allow for manipulation of ancillary support equipment (e.g., ventilators, oxygen, monitors, intravenous drips with pressure bags, chest tubes, etc.) on-board the aircraft without impairing access to the patient. Additionally, weight bearing and prevention of pressure sores and skin erosion should be considered when developing materials for this device. Finally radiological and surgical considerations (e.g. access to wounds of the side and back) should be taken into account when developing the immobilization device and materials not compatible with X-Ray or Computed Tomography should be avoided.

Requirements of the system include:
1. Ability to fit in NATO standard litter restraints/ Compatible with standard Over Sized Litter (OSL).
2. Immobilization for patients with unstable cervical spine trauma and for unstable thoracic and lumbar spine injury.
3. Transportable via most fixed wing and rotary Air Evac aircraft
4. Permit access for medical treatment and airway control and permit prone and supine transport as well as access to back-wounds/surgical sites.
5. Man-portable to enable CCAT & AE teams to safely transport spinal injuries using 2-4 person carry.
6. If stand-alone carrier, must accommodate AE approved med pumps, vital signs monitor, and oxygen, preferably below the patient.
7. If an air or liquid based mattress is used, should include closed loop control system to monitor and respond to developing pressure points on patient.

8. Air or liquid based systems should also be capable of closed loop adjustments for changes in pressure with altitude change.
9. Splint systems must be able to monitor pressure points and adjust to reduce pressure on patient.
10. Must permit raising or lowering patient's head to manage intracranial pressure and comfort.
11. Utilizes novel self cleaning or easily cleaned liquid-proof materials to enable keeping patient dry.
12. Must be able to be used with emerging advanced litter systems (LSTAT, LSTAT Lite, etc. This is preferable) if not a stand alone system.
13. Monitoring systems must be capable of being integrated with existing/planned monitoring systems for advanced litters.
14. Must include ability to warm patient and potentially cool patient if practical application can be developed.
15. Patient must be able to remain in system for a minimum of 12 hours without incurring additional morbidity/injury.

PHASE I: The goal of this phase is to assess the requirements and then demonstrate the feasibility of developing a lightweight, pressure and shock absorbing transport system to improve stabilization of subjects with traumatic brain (TBI) and spine injuries during fixed wing and rotary air evacuations. Evaluation of forces acting upon patients, and patient's ability to tolerate these forces will occur during this phase. A review of ancillary devices and weight restrictions required for transportation should also occur. A review of current and emerging technologies to include: investigation of materials and systems to prevent skin ulceration; assessment of rapid setting foams for splinting; air or spring systems; fluid shock absorbers; integrated pressure monitors and controllers should be completed. Phase I will result in design plans and documents, and model systems resulting from the assessment.

PHASE II: Based upon the data and design plans obtained in Phase I, the awardee will develop a prototype of the stabilization system. Development of field test objectives and conducting limited testing demonstrating airworthiness should also occur in this phase. The Required Phase II deliverables will include a well-defined prototype that addresses the requirements discussed above. Initial FDA review requirements will be addressed.

PHASE III: Secondary injuries resulting from transport of traumatically injured patients is preventable with an appropriate mobilization system. The development of such a system will have widespread application for care of neurosurgical patients in both military and civilian sectors. The safe transport could clinically improve the outcome and subsequent cognitive rehabilitation, by preventing additional secondary neurologic decline as a result of the extreme forces exerted on the patient in the aircraft. Success of this endeavor would provide improved medical-evacuation of civilian trauma patients from remote locations where trauma might be due to motor vehicle or water craft accidents, mountain climbing, falls, etc. It may also be used as an additional tool for the US Coast Guard in the prevention of secondary trauma when transporting victims by USCG boats or aircraft.

The prototype developed in Phase II will be further evaluated in Phase III for transition into a viable product for sale to the military and private sector markets. A plan including how FDA approval will be achieved, utilizing current Good Manufacturing Practices (cGMP), Quality Management and device applications will be developed and executed. Appropriate acquisition authorities within the Army medical department will be engaged should a successful solution result.

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KEYWORDS: Aeromedical evacuation, Litter, Stabilization, Immobilization, Spinal Cord Injury, SCI, Transport, Traumatic Brain Injury, TBI, Spine Injury, evacuation

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OSD09-H14 TITLE: Virtual Evacuation Vehicles for Training Medics (VEV-TM)

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To design and develop a scenario-based virtual training tool for the Mine Resistant Ambush Protected (MRAP) vehicle/Heavy Armored Ground Ambulance (HAGA); such that military medical personnel can practice loading and unloading patients in a realistic virtual world that provides feedback to the trainee and maintains a record of performance. The first time medics will see the new vehicles will be in theatre; thus creating a critical training gap. Through use of virtual training medics will gain valuable experience and exposure to the required processes in a pre-theatre environment potentially reducing time delay issues, safety, and survivability considerations caused by inexperience. This virtual environment has the potential to be used by all military medical personnel during state side training.

DESCRIPTION: In current theaters of operation ground ambulances are not used outside the forward operating bases. The Army is faced with replacing the current ground evacuation vehicle with the new MRAP Heavy Armored Ground Ambulance (HAGA) version. These armored vehicles are going straight to Iraq and Afghanistan. This new Ground Ambulance called the HAGA is an upgraded vehicle from the MRAP and is used for evacuation of patients in theatre.

Army medics will not have the opportunity to train “casualty evacuation” on these new ambulances during medical training; instead they must wait until they get to Iraq or Afghanistan. This is a capability gap, not only will loading and unloading patients be needed, but additional medical equipment can be brought with the evacuation asset to augment the equipment the medic currently has. HAGA’s payload and advanced design features allow the medic to administer to three critical patients in reconfigurable litter stations. When the litter racks are folded in a stowed position, the medic can attend to as many as six ambulatory patients in a bench seating configuration. Additionally, the HAGA has more storage capacity for medical care items, medical equipment, and oxygen tanks compared to current force medical vehicles. It also has state-of-the-art exterior and interior lighting systems for patient care and features four headsets for improved internal communication.

Patient care scenarios need to be practiced and rehearsed prior to deployment. Currently only HAGA operators receive a five-day training course teaching Soldiers how to operate and maintain the ambulances. Training needs to be provided to combat medics as well. There are many advantages of virtual training systems, such as the benefits of the cost saving of gas, reducing damage of using the real vehicles, maintenance cost, and spare parts. This topic will implement the concepts of crawl, walk and run: using the computer base training first, then real vehicles and finally being in theater. These low-cost simulations will provide medics with a virtual walk through of these new ambulances where they can practice and rehearse using the medical equipment that is now built into the HAGA.

This virtual walk through would also give students an idea of where the medical equipment is located in the vehicle and what it is used for. Most ambulance mockups do not include the medical equipment set, so a virtual computer simulation would help them understand what is available and what it is used for. Communication could also be practiced at the "point of injury" to the next level of care (Battalion Aide Station) with communication of injuries, treatments given, etc. during this hand-off of the patient. Interviews coming back from medical personnel in theatre state that lack of current training have caused safety and survivability considerations, such as not enough space to work on patients; don't know how to use equipment, not enough storage space, etc. Individual body armor had to be removed to move around the inside of the HAGA due to limited space. Medics were not ready to use the MRAP/HAGA.

The goal of this SBIR effort would be to explore current and emerging technologies that offer new, innovative approaches to provide realistic, relevant, anywhere, anytime training for the Army medic. Another goal is to provide accurate feedback on performance of the trainee. It has been shown that virtual simulations effectively prepare Soldiers for real war.

PHASE I: Conduct a feasibility study and describe overall system architecture for a medical virtual training system that trains the tasks during casualty evacuation of a patient. This system should use scenario based training exercises for use in the current training Program of Instruction (POI) at the Department of Combat Medic Training (DCMT) Ft Sam Houston Texas. DCMT supports this effort, as they requested a system such as a virtual evacuation trainer to be used for training medics in the Tactical Combat Casualty Care course. Training Objectives and performance metrics should be identified during this phase.

PHASE II: Develop, test and demonstrate a prototype system from the recommended solution in Phase I. Provide realistic and meaningful interaction for medics with a new virtual MRAP Vehicle/ ambulance in a relevant Training environment.

PHASE III: This system could be used in a broad range of military medical training applications. The software shall have the capabilities to train the medic teams with various platforms of ambulance vehicles. Demonstrate the application of this system to combat medics and other military personnel.

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10. http://www.cs.amedd.army.mil/68w/HQ/HQ.htm

KEYWORDS: Mine Resistant Ambush Protected Vehicle, MRAP Vehicle, CASEVAC, Combat Medic Training, Medical, Simulation, Heavy Armored Ground Ambulance, virtual environments, military training, HAGA, 68W, tactical combat casualty care, TCCC

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OSD09-H15 TITLE: Non-Contact Monitor for Patients with Sleep Disorder

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop a portable non-invasive, non-contact sleep monitor for accurate assessment of physiological indicators associated with acute and post-traumatic stress disorder (PTSD) or effects from traumatic brain injury (TBI).

DESCRIPTION: Research conducted by Walter Reed Army Institute of Research (WRAIR) has shown that 20-40% of Soldiers returning from Iraq and Afghanistan experience mental health problems serious enough to impair social or work function, including Post-traumatic Stress Disorder (PTSD). Recent studies suggested that PTSD is often associated with concussion, a mild form of traumatic brain injury (TBI). WRAIR studies also showed that more than half of Soldiers identified with serious behavioral health related symptoms did not seek treatment [1]. Identification of affected or at-risk soldiers is key to early intervention and successful treatment. For sufferers of PTSD, sleep disturbances are among the most treatment-resistant symptoms and can lead to drug and alcohol abuse, even suicide [2]. While fully attended polysomnography (PSG) carried out in dedicated sleep laboratories (Type-I monitoring) has proven effective in diagnosis and treatment of certain types of sleep disorders, such contact-sensor-based procedures are both invasive and expensive, and can only be expected to reach a small portions of those affected. A portable, non-contact sleep monitoring system provides a highly accurate diagnostics tool which can be used in the hospital or at home that does not interfere with patients' sleep, and provides a robust solution that is non-invasive and economical enough to be referred to all soldiers returning from combat, with the aim of identifying those most at risk [3]. We are seeking innovative and creative research and development efforts, for example Doppler radar based, that would benefit Battle Casualty and Psychological Health Research addressing diagnosis, treatment, and mitigation of deployment related injuries and psychological health concerns. This is in accordance with the Military Operational Medicine Research Program to manage efforts directed toward Suicide Prevention and Counseling Research.

PHASE I: Conduct research to provide a proof of concept demonstration of a non-contact, portable, sleep disorder monitoring prototype. The concept will be original or will represent significant extensions, applications, or improvements over published approaches and the current technological limitations described above. Design and performance considerations for a proof of concept demonstration are listed below.
1. The prototype system must include measurement of two respiratory variables (e.g., respiratory movement and airflow), and a cardiac variable (e.g.., heart rate or electrocardiogram).
2. The prototype system must be portable, non-invasive and non-contact to the patient, and completely independent of the sleeping surface.
3. The prototype system must include an automated wireless interface for data transfer from the sensors to a remote processing unit.
4. The prototype system must include positive subject identification, including interference from subjects in the proximity of the wireless signal.
5. The prototype system must be capable of collecting data for at least 24 hours, and transitioning to a battery operated device.

PHASE II: Validate the Phase I prototype by demonstrating performance comparable to attended sleep laboratory technology, but suitable for unattended use. Develop, test and demonstrate diagnostic capability with built-in alarms.

Test system performance under different environmental conditions to ensure accurate operation in field, hospital, and home environments likely to be encountered for use.

PHASE III: There are clear commercial opportunities for an unobtrusive, non-contact sleep monitor, based on patterns of respiration [4,5]. The major military applications are for PTSD and TBI diagnostics and monitoring in field, hospital and home environments. The major civilian application for this technology is next generation of sleep monitoring devices for obstructive sleep apnea (OSA). Research indicates that 40 million Americans suffer from insomnia and chronic sleep disorders, with over 12 million Americans suffering from OSA. The estimated direct annual cost for OSA is estimated at $16 billion [6].

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KEYWORDS: Sleep monitoring, wireless, PTSD, TBI, polysomnography, mental health

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OSD09-H16 TITLE: Medical Capability Simulator Interface Tool for OneSAF

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To design and develop an open systems specification and interface tool prototype for interfacing combat casualty care medical capabilities and devices (real or simulated) to the Army’s One Semiautonomous Forces (OneSAF) computer generated forces simulation system so that potential for combat use of emerging medical capabilities and technologies can be assessed and evaluated at Army Battle Labs within tactical exercises and simulations. Output data and conclusions from such exercises are essential to development of tactics, techniques, and procedures (TTPs) and identification of both functional and technical requirements for generation of capabilities documentation under Joint Capabilities Integration and Development System (JCIDS).

DESCRIPTION: Traditionally the Army has used a concepts, now capabilities, based development system for introducing new technologies into the battlefield. Essentially this is a serial process which involves time consuming analysis of operational problems combat developers who consider a wide variety of approaches to filling gaps in current operational doctrine and procedures. Working through this long and cumbersome process often results in technologies which are already obsolete upon fielding or no longer meet the operational needs of the users. Various attempts have been made to shorten or circumvent this serial process including introducing a “rapid equipping force" to take technologies directly to the battlefield for testing with troops and so-called "spiral development" which portends to field technologies or system components when ready, regardless of the technology readiness of the overall system for which they are being developed. Inherent in these approaches is the Battle Lab, where the Combat Developers can experiment with new concepts and technologies in simulated or live exercises with or without troops to generate or validate new concepts. Integration of new technology into Battle Lab exercises early in its development with direct participation from the Materiel Developers including the Science and Technology subject matter experts has been shown to greatly improve both the combat and materiel development processes. Full integration of new and emerging technologies within Battle Lab operational exercises and assessments first requires integration of the technology and its physical characteristics and candidate tactics, techniques, and procedures within the Battle Labs' operational simulation programs. If conducted early on in the prototyping process rather than after a prototype is considered "ready for transition", the process of conducting repetitive integrated simulated and live user exercises with both computer models of new and disruptive technologies and working prototypes has great potential for both speeding up and improving the design and development process. Currently there are no suitable physical or operational simulation models of emerging medical technologies within the operational simulation system most prevalent at Army Battle Labs, i.e. OneSAF (Simulated Autonomous Forces) (Refs 1-4, 9-10). Likewise there are no combat casualty or patient models within OneSAF that can be used to assess or evaluate the effectiveness of a new medical technology or treatment technique when used by a combat life saver or combat medic during small unit maneuver exercises or simulations. An open systems specification and interface tool prototype for interfacing combat casualty care medical capabilities and devices (real or simulated) to the OneSAF computer generated forces simulation system is needed in order to conduct operational assessments and evaluations of potential combat use of emerging medical capabilities and technologies at Army Battle Labs. Such a tool would also likely require a patient physiological model from which to measure the effects of the candidate medical capability or technology on casualty survivability and outcomes. (Refs. 5-6). Additionally, model interface with OneSAF must be High Level Architecture (HLA)/Distributed Interaction Simulation (DIS)) IEEE 1516, IEEE 1278 compliant (Refs 9,10). For simulations that are intended for the Army Future Combat Systems Command and Control, the preferred language is Battlefield Management Language (BML) (Ref 11).

PHASE I: Design and show a proof of concept for an open systems specification and interface tool prototype for interfacing combat casualty care medical capabilities and devices (real or simulated) to the Army's One Semiautonomous Forces (OneSAF) computer generated forces simulation system so that potential for combat use of emerging medical capabilities and technologies can be assessed and evaluated at Army Battle Labs within tactical exercises and simulations. Conduct a market survey of relevant military and potential civilian applications, such as emergency first responder simulation systems used by government (e.g. Department of Homeland Security), private or volunteer emergency services organizations to train first responders and assess new medical first responder technologies for natural disasters and other civilian emergencies; prepare an initial commercialization plan for the Phase II proposal.

PHASE II: Prototype and demonstrate the Phase I open systems specification and interface tool prototype for interfacing combat casualty care medical capabilities and devices (real or simulated) to the Army's One Semiautonomous Forces (OneSAF) computer generated forces simulation system so that potential for combat use of emerging medical capabilities and technologies can be assessed and evaluated at Army Battle Labs within tactical exercises and simulations. Using the prototype tool demonstrate generation of working OneSAF models for four emerging medical first responder technology prototypes suitable for use by combat lifesavers and combat medics during infantry platoon offensive operational exercises, such as might be run at the Fort Benning Maneuver Battle Lab. The four prototype technologies should include: 1) an automated casualty assessment or triage tool, 2) a robotic assisted casualty extraction system, 3) a first aid tool such as the one-hand tourniquet and 4) an emerging enroute care technology such as the portable hand-held field fluid/blood warmer or the Life Support for Trauma and Transport – Light (LSTAT-Lite) (Refs 7-8). Demonstrate measurement of the effect of the first responder's employment of these technical capabilities on casualty survivability and outcome via a working patient physiological model. Prepare a more detailed Phase III commercialization plan based on detailed analysis of the Phase I market survey of relevant military acquisition programs and potential civilian applications.

PHASE III: Assist Government technical monitor in transitioning to the Army Training and Doctrine Command (TRADOC) Battle Labs, the open systems specification and interface tool prototype for interfacing combat casualty care medical capabilities and devices (real or simulated) to the Army's One Semiautonomous Forces (OneSAF) computer generated forces simulation system so that potential for combat use of emerging medical capabilities and technologies can be assessed and evaluated at Army Battle Labs within tactical exercises and simulations. Execute the commercialization plan developed in Phase II extending the model generation tool to other relevant military and potential civilian applications identified in the market survey, such as emergency first responder simulation systems used by government (e.g. Department of Homeland Security), private or volunteer emergency services organizations to train first responders and assess new medical first responder technologies for natural disasters and other civilian emergencies.

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KEYWORDS: OneSAF, modeling, simulation, Battle Lab, trauma model, LSTAT-Lite, first responder, operational assessment

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OSD09-H17 TITLE: Novel Biomaterials for Complex Tissue Repair and Reconstructive Surgery of Traumatic Injuries

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop novel, biodegradable/resorbable biomaterials that will promote tissue and/or bone healing, resulting in eventual tissue and/or bone replacement of complex tissue injuries due to traumatic assault (in particular, complex injuries to the extremities and face that requires complex tissue engineering for repair of bone, muscle, tendon, cartilage, and skin). The biomaterial should be off-the-shelf use and should provide an environment that will support cell growth (at least 1 cubic centimeter), differentiation, revascularization, and communicate with the injured environment to minimize inflammation and/or prevent/minimize infection.

DESCRIPTION: Due to advances in body armor and the preferred choice of weapons being explosive devices used against the war fighters in the Global War on Terrorism campaigns, extremity injuries have grown in its contribution to morbidity and mortality. The nature of warfare has changed from previous wars where the enemies will continue to use this type of weapon to inflict maximum damages at low cost. These resulting injuries are complex such as comminuted fractures as well as composite musculoskeletal and nerve tissue loss, where some part of the extremity is viable but lack of optimal treatment options sometimes necessitate limb amputation versus reconstruction surgeries that could lead to optimal/normal functional restoration and outcome. In cases of facial injuries, the current reconstructive options require multiple rounds of surgeries, and powerful pain medication that must be weaned off each time that do not even come close to desirable outcome in terms of both aesthetics and function. Such injuries also accounts for significant number of war fighter’s not fit for returned to duty status, longest average inpatient stay, accounting for 65% of the $65.3 million total inpatient resource utilization, and 64% of the $170 million total projected disability benefit costs and extrapolating this cost could yield total disability costs of $2 billion (1). Aside from the cost issues, all injured warfighters want to live and function like their pre-injured state. Advances in stem cell science, biomaterials, and tissue engineering could help in repairing/restoring damaged complex tissue (i.e. nerve, muscle, and tendon) resulting from direct impact of traumatic injury or due to secondary mechanisms of damage such as compartment syndrome (2-5). Current developments often focus on developing biomaterials for tissue engineering and regeneration of a single tissue type, while the injuries are often complex tissue loss. There is a need to develop novel, biodegradable/resorbable biomaterials combined with advances in (stem) cell biology/development and tissue engineering, to engineer an environment capable of supporting cell growth, differentiation, revascularization, and communicate with the injured environment to minimize inflammation and/or prevent/minimize infection.

PHASE I: Develop novel, biodegradable/resorbable biomaterials that will promote complex tissue and/or bone healing, resulting in eventual tissue and/or bone replacement of complex tissue injuries. The biomaterial should be off-the-shelf use and should provide an environment that will support cell growth (at least 1 cubic centimeter), differentiation, revascularization, and communicate with the injured environment to minimize inflammation and/or prevent/minimize infection. Determine optimal biomaterial and its structure/function that will result in regeneration of functional, complex tissue (at least 1 cubic centimeter) in vitro with intrinsic properties representative of the native tissue.

PHASE II: Test the efficacy of the biomaterials in small animal model with an injury model representative of the complex tissue injury/loss. Assess the biomaterial for its ability for regeneration and re-integration with surrounding tissue and functional outcome. Establish performance parameters of the biomaterials for the injury model. Assess the safety. Optimize the parameters and develop plans for large animal, pre-clinical studies.

PHASE III: Conduct large animal, pre-clinical studies based on results from phase II. The end result would be an off-the-shelf biomaterial with established performance parameters including cell types, ratio, cell solution, signaling factors, and biomaterial structure/architecture, that can be produced for human clinical studies in reconstructive surgery of repairing complex tissue injuries. It must be easy to use and should result in both aesthetic and functional outcome.

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KEYWORDS: Biomaterials, Tissue engineering, Stem Cell, Cell Signaling, Cranio-facial/extremity injury

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OSD09-H18 TITLE: Remote Monitoring and Diagnosis of Warfighters at Risk for PTSD

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: The objective of this topic is to develop a non-intrusive tool for remote monitoring/screening of the injured warfighters' mental health status during their recovery period following an injury. Ideally, this non-invasive tool would provide important information regarding a warfighter's mental health status through detection and monitoring of biological patterns and/or signals (e.g. based on normal phone conversations).

DESCRIPTION: According to a study published in the New England Journal of Medicine in 2004 (Hoge CW, Castro CA, Messer SC, et al. Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. New England Journal of Medicine. 2004;351(1):13-22), it is estimated at the high-end that the prevalence of Post Traumatic Stress Disorder (PTSD) for both Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) combined is almost 20%. Although Congress has allocated $900 million for improvement in mental health care access, suicide rates have not been reduced. These programs include outpatient treatments, hotlines and various forms of group and individual therapies including those conducted in person clinics or through the web or virtual reality. Approximately 10 to 20 percent of troops have screened positive for PTSD during redeployment (recent testimony provided by Army Brig. Gen. Loree Sutton, Director of the Defense Center of Excellence for Psychological Health and Traumatic Brain Injury, during 3 March 2009 Congressional hearing). PTSD, depression, and other mental health concerns are often difficult to diagnose due to overlapping symptoms as well as issues of stigma associated with mental illness which may cause service members to underreport psychological distress. Thus, there is a need to develop an effective, low cost, non-intrusive tool for remote monitoring/screening of the warfighter's mental health status.

Ideally, a non-invasive tool could be developed that determines a warfighter's mental health status through detection of biological patterns and/or signals (e.g. identification of changes in the respondent's biological patterns/signals based on normal conversations through the phone either with a care provider or through interactive voice response). Recent studies on PTSD, as well as past studies on other mental illnesses indicate that many mental disorders have specific speech and language processing deficits which potentially may lead themselves to detection through voice signal/pattern recognition technologies. In the case of voice signal/pattern detection, such a tool should be designed to mitigate possible answers that would throw off survey-based tools/assessments (i.e. the signal/pattern detection tool should be response/context independent). Since the military force comes from diverse backgrounds (i.e. culture, ethnic, and race), this tool needs to be applicable across various military members' backgrounds. Clinical studies will need to be developed later for validation of this methodology. Further, it is envisioned such a tool could be integrated into other DoD/Army funded efforts such as the Tele-TBI program and/or the FY08 SBIR "Interactive Cognitive Interface and Health Monitoring System."

PHASE I: Develop and conduct proof of concept with a demonstration of feasibility and potential efficacy.

PHASE II: Examination of the use of this technology for screening and diagnosis using a well designed, randomized controlled trial, delineating the sensitivity and specificity of the technology compared to gold standard methods of clinical diagnosis (e.g. clinical Clinician-Administered PTSD Scale (CAPS) interview). This phase should also demonstrate the capacity of this technology to assess global changes in symptoms and functioning.

PHASE III: Modeling the tool for clinical deployment. Integration of the developed tool into other DoD/Army funded efforts such as Tele-TBI program and standard clinical settings within the DOD. It is anticipated this tool could be used for remote monitoring and diagnosis of soldiers at risk for PTSD, depression, or other mental health issues including those stationed at overseas mission as well as those returning from deployments. Such a system could aid in the early identification of individuals in need of treatment.

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KEYWORDS: PTSD, remote monitoring, biological signals, non-invasive, diagnostics

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OSD09-H19 TITLE: Development of a universal method for diagnostic sample inactivation, extraction and enrichment of pathogens in arthropod hosts of military importance.

TECHNOLOGY AREAS: Chemical/Bio Defense, Biomedical

OBJECTIVE: Develop a universal method for pre-analytical specimen processing to identify pathogenic viruses, rickettsia and non-rickettsial bacteria included in the Department of Health and Human Services/Centers for Disease Control and Prevention Listing of Select Agents that propagate and/or disseminate in arthropod host vectors (herein referred to as Agents). Method should include extraction and enrichment of molecular assay biomarkers and must be verifiably inactivate Agents without compromising the integrity of the specimen for storage or further testing.

DESCRIPTION: Requirement: Early detection of Agents is crucial to prevent casualties during natural or induced outbreaks resulting from the dissemination of Agents involving arthropod vectors. Identification of Agents that have a natural or an accidental life cycle in arthropods is key to the protection of highly susceptible populations such as military personnel deployed to endemic areas where natural outbreaks occur and first responders of induced outbreaks. Sensitive and accurate Agent identification using specific genomic, proteomic or other molecular biomarkers is paramount for the creation of effective vaccines and therapeutics to control spread of disease in endemic areas and prevent subsequent natural outbreaks, as well as to monitor and deter induced outbreaks or releases. Human and animal arthropod-borne disease control measures will depend on availability of highly specific and sensitive diagnostic testing in a field setting or transfer to a reference or research laboratory facility. Sample specimens will need to be able to processed immediately or preserved for at least twenty four hours without refrigeration.

Desired capability/concept of final product: Since the target detection systems are often limited in their front-end sample handling capabilities, often relying upon separate, pre-analytical sample processes, such as extraction, amplification and purification. Circumventing this will require a secure, robust and versatile pre-analytical specimen processing to provide a timely relevant sample for analysis. The improved method should:
• Allow for the processing of arthropod specimens for the presence of Agents, to include (a) measures to insure containment, (b) Agent inactivation, (c) cross-contamination control, and (d) preservation of multiple analytes for analysis.
• Provide for rapid extraction of target molecules into solutions including some ‘difficult-to-lyse’ organisms for rapid Agent detection assays within predetermined processing timeframe applicable to each Agent (examples: 1 hour for West Nile Virus, 24 hours for Yersinia pestis).
• Include a method to remove lysis reagents before detection methods are applied if demonstrated that these reagents interfere with test results.
• Allow for pre-analytical processing at either the sample collection site or a central laboratory. Thus, both portable and high throughput assays can be performed either on-site or in central laboratories
• Be equally suitable for measurement of a variety of molecular targets including, but not limited to, both nucleic acids and proteins.

PHASE I: Selected contractor will demonstrate proof-of-concept for a pre-analytical sample processes method by comparison of proposed method with ‘standard method’. In cases where a standard method may not be available, a comparison should be made with a published method evaluated by the Armed Forces Pest Management Board. Comparisons should be made in relation to:
• Length of time to prepare sample
• Cost and availability of reagents and equipment
• Analytical test genomic, proteome or other biomarker results
• Fold enrichment characteristics of final sample size
• Demonstration of sample use in multiple biomarker assays
• Natural and accelerated stability profiles including ambient and refrigerator conditions

In addition the method must possess the following features:
• Security: Allow for the collection, transport, processing, and inactivation of samples in a closed system, thus maintaining the maximum chain-of-custody security.
• Safety: The specimen container needs to be a safe-to-use general purpose multifunctional device for the collection, transport, possible cultivation, and processing of Agents. It must be resistant to breakage, thus reducing the likelihood of exposure to hazardous materials. Chambers to manipulate specimens must prove to offer safeguards against aerosolization when specimen container is opened. In the event of a contamination to the outside of the specimen container, the chamber must be resistant to treatment with an effective disinfectant and pose minimal danger of operator exposure to potentially pathogenic organisms.

• Ease-of-use: It is possible that in combat situations, lesser skilled personal may be required to collect or even process samples for transport. Therefore, ease-of-use procedures must be demonstrated for less experienced military personnel.
• Speed: The device and methods needs to significantly reduce the time to result through more efficient processing methods. Reducing the length of time of pre-analytical specimen processing to five minutes is to be demonstrated.
• Breadth of Application: Extraction methodologies must be: 1) suitable for multiple arthropods 2) effective for difficult-to-lyse organisms, such as ticks with chitaneous exoskeletons and 3) allow analysis of multiple biochemical parameters from the same sample.
• Field utility: If not yet achieved, provide a business plan for use of instrument procedures and handling processes in forward hospital or field environments.
The ability of the method to meet these criteria will be evaluated at a government laboratory.

PHASE II: The goal is the development and delivery of a portable device for field applications that demonstrates the features and capabilities of the instrument demonstrated in Phase I, as well as:
• Have a 96-well format for high-throughput capability
• Possess a reliable temporary power supply and be able to run off a 12/24V battery
• Be small, lightweight, portable ruggedized for transport and use
• Function in an unstable temperature and humidity environment

Optimization of method needs to be demonstrated by analysis of known analytes using the following criteria in a field setting:
• Stability: Sample preparation must be optimized by physical measurements such a temperature stability over time. For example: West Nile virus isolated from mosquitoes, Yersinia pestis from fleas and Crimean Congo hemorrhagic fever virus from ticks
• Sensitivity: The ability to detect analyte in the expected range of detection for an assay
• Specificity: The ability to decipher Agent(s) in a single arthropod
• Agent inactivation: Use of the most sensitive detection assay for the particular Agent. Test material should include negative and positive strand RNA viruses, a DNA virus, and rickettsial and non-rickettsial bacteria.

PHASE III: This method will be suitable for use by biomedical researchers as well as far-forward military and first responders.
In addition, applicability for such a method can be marketed to a variety of commercial medical organizations for:
• Adventitious agent-free banked blood
• Transfer of reagents and specimens to a lower level of containment in academia and government laboratories with maximum biological containment facilities
• DNA/RNA/antigen stabilized samples for forensic and military DNA identification repositories

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KEYWORDS: Arthropods, field-deployable, sample enrichment, inactivation, bioweapon, infectious disease

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OSD09-H20 TITLE: Development of a hand-held, field-deployable multiplex assay for the detection of Chikungunya Virus (CHIKV), West Nile Virus (WNV), and Dengue Virus in mosquitoes.

TECHNOLOGY AREAS: Materials/Processes, Biomedical

OBJECTIVE: Adapt state-of-the-art technology to develop a hand-held, field-deployable assay capable of detecting and identifying, with one assay, CHIKV, WNV, and Dengue in mosquitoes collected from deployed military service areas. These three diseases are the militarily-important pathogens prioritized on the ID-IDEAL ranking.

DESCRIPTION: Development of this assay is an extremely high priority to the Department of Defense, allowing rapid determination of infected mosquitoes and timely implementation of prevention and control programs to minimize the impact of the diseases in deployed US forces.

REQUIREMENT: To quickly and accurately determine whether mosquitoes collected during military deployments are infected with CHIKV, WNV, and/or Dengue, the three most militarily-relevant mosquitoes diseases, to minimize the impact of the disease on our operational capabilities and minimize medical evacuation and lost-duty time. Rapid identification of the pathogen should occur as far-forward as possible, and the testing methodology must be easily portable, shelf-stable, and cost effective.
A. Desired Capability/Concept of the Final Product: We envision a rapid multiplexed detection hand-held assay capable of simultaneously determining whether mosquitoes are infected with CHIKV, WNV, and/or Dengue. The assay shall detect a large range of serotypes and strains of CHIKV, WNV, and/or Dengue. The assay shall at least detect minimum 10e5 viral particles of CHIKV, WNV, and/or Dengue (each). The assay shall be rapid (<30 min), one- or two-step format, and stable (storage at 35ºC for 2 years). The assay shall be at least 80% as specific and at least 80% as sensitive compared to current gold-standard assays (real time PCR, plaque assay and/or ELISA) and shall require a small (<100ul) sample volume. The assay shall be soldier-friendly (i.e., easy to operate), inexpensive, portable, use heat-stable reagents, and have no special storage requirements.
B. Technical Risk: There is a degree of technical risk involved in this project. There are currently no existing assays that meet the requirements outlined in this proposal. The candidate contractor is expected to use innovation and in-house expertise to develop a prototype that meets the needs of the Department of Defense.
C. Access to Government Facilities and Supplies: Reagents, positive-control materials, infected mosquitoes, etc, to support this project may be available from the Walter Reed Army Institute of Research (WRAIR) and US Army Medical Research Institute of Infection Diseases (USAMMRIID). The candidate contractor should coordinate with the Contracting Officer Representative (COR) for any support required from WRAIR.

PHASE I: Selected contractor shall determine the feasibility of the concept by developing a prototype diagnostic assay that has the potential to meet the broad needs discussed in this topic. Contractor shall conduct initial laboratory evaluation of the prototype device and provide a written report to COR. By the conclusion of Phase I, the selected contractor shall provide a single lot of 100 prototype assays to the COR. The degree to which the prototype assay meets the desired capability outlined above will be evaluated at a government laboratory – data from this independent evaluation will be used in the determination of the Phase II awardee.

PHASE II: The goal in Phase II is the development of a prototype assay that provides at least 80% sensitivity and at least 80% specificity when compared to current gold standard assays for each CHIKV, WNV, and Dengue. Once sensitivity/specificity requirements have been met, the selected contractor shall conduct comprehensive laboratory evaluation of the assay performance characteristics (sensitivity, specificity, positive and negative predictive value, accuracy and reliability) and initial field testing. By the conclusion of Phase II, the selected contractor shall provide a single lot of 1000 prototype assays to the COR.

The selected contractor shall also conduct stability testing of the device in Phase II. Stability testing should be conducted under both real-time and accelerated (attempt to force the product to fail under a broad range of temperature and humidity conditions and extremes) conditions.

The WRAIR or USAMRIID may provide support to facilitate the test and evaluation of the developed device. The selected contractor shall coordinate in advance with the COR for any support required from the WRAIR or USAMRIID.

It is envisioned to have a universal hand-held device; therefore the Phase II proposal must include a detailed description of the strains and serotypes (of the pathogen) that will be used for the evaluation.

PHASE III: During this phase the performance of the assay should be evaluated in a variety of field studies that will conclusively demonstrate that the assay meets the requirements of this topic. By the conclusion of this phase the selected contractor will have completed the development of the assay and successfully commercialized the product. The contractor shall provide a report that summarizes the performance of the assay to the Armed Forces Pest Management Board and will request that a national stock number (NSN) be assigned. Contractor shall coordinate in advance with the COR for any support required from the WRAIR or USAMMRIID.

Military Application: Once an NSN has been assigned to the assay, the Armed Forces Pest Management Board will work with appropriate organizations to have the assay incorporated into appropriated “sets, kits, and outfits” that are used by deployed Preventive Medicine Units.

Commercial Applications: This assay will also be available for non-military purposes, such as use by commercial pest controllers or non-governmental organizations (NGOs) in areas of the world where CHIKV, WNV, and Dengue are endemic. We envision that the contractor that develops the CHIKV, WNV, and Dengue assay will be able to market this assay to a variety of commercial, governmental, and non-governmental vector control organizations, and that this market will be adequate to sustain the continued production of this device. By the end of this phase, the selected contractor shall make this product available to potential users throughout the world.

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KEYWORDS: Chikungunya, CHIKV, West Nile, WNV, Dengue, detection, assay, next- generation, field-deployable, diagnostic, device

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OSD09-H21 TITLE: Develop Field-usable Diagnostic Devices for the Specific Detection of Leishmania Major and L. Infantum in Sand Flies

TECHNOLOGY AREAS: Materials/Processes, Biomedical

OBJECTIVE: Produce a standalone assay in the form of a device or kit practical for use in unaccommodating environments that can be used by personnel with minimum scientific background that is capable of identifying, when present in sand flies, cutaneous L. major and visceral L. infantum.

DESCRIPTION: The purpose of this solicitation is to develop an assay to quickly determine, in a non-laboratory and minimal resource environment, whether sand flies collected in specific areas of a military deployment are infected with either L. major or L. infantum. These are the most ubiquitous species of Leishmania found in many parts of the mid-east. During Operation Iraqi Freedom, over 99% of the leishmaniasis contracted by US soldiers were L. major, however, L. infantum, a latent visceral infection, accounts for about half of the leishmaniasis cases in areas of Iraq.

Leishmania is not prevented by vaccines or prophylactic drugs so prevention relies on personal protective measures (PPM's) and vector control measures that need to be targeted to be effective at reducing disease risk. Surveillance is necessary to targeting where vector control and PPM's need to be implemented, and also provide information on the type of intervention needed. Vector surveillance consists of determining the specific vectors present in an area, their abundance, and infection rates. This data is then used to determine risk of disease. The severity of the threat depends on the abundance of infected sand flies. Areas without infected sand flies or with very low numbers of infected sand flies pose minimal risk to US military forces. Conversely, areas with high numbers of infected sand flies pose a severe risk and require aggressive implementation of prevention and control measures. High risk areas need prompt and efficient measures to prevent transmission. During the first two years of Operation Iraqi Freedom, around 2,000 confirmed and suspected cases of leishmaniasis occurred. Coleman, et. al. predicted this risked based on vector surveillance using PCR to identify infected sand flies.

PCR assays, however, require equipment, reagents and training that are not available outside of a permanent or semi-permanent facility. Army, Navy and Air force Preventive Medicine detachments (PVNTMED DETs) are normally deployed throughout a theater of operations. A primary mission of these detachments is to conduct pest control operations. PVNTMED DETS currently are equipped with the Malaria Vec-Test, a field-usable assay for the detection of malaria in mosquitoes. The Malaria Vec-Test allows PVNTMED DETs to accurately conduct their own malaria threat assessment, and the results from this assessment allow the PVNTMED DETs to rapidly and efficiently implement targeted pest control operations. No similar field-usable assay currently exists for the detection of leishmaniasis in sand flies. Such a rapid field-usable assay would allow PVNTMED DETs to determine whether or not a Leishmania risk existed at their surveillance sites without having to wait for offsite PCR assays to be completed. An initial indication of risk would set in motion measures to reduce the risk leishmaniasis to soldiers entering the area. Due to the current critical threat posed by leishmaniasis to US forces deployed to the Middle East, this effort is a high priority for the DoD.

DESIRED CAPABILITY/CONCEPT OF THE FINAL PRODUCT: A rapid detection assay that is capable of determining whether sand flies are infected with either L. major or L. infantum is needed. The assay must be usable outside of the laboratory by minimally trained personnel. The assay should detect Leishmania species specific antigen OR an alternative marker that is specific for each of these species. The assay must be rapid (<30 min), a one- or two-step format, and stable (storage at 35 degrees C for 2 years). The assay should be sensitive enough to detect 1 sand fly infected with 1000 promastigotes in a pool of 25 sand flies, and should be specific enough to detect the correct infection 90% of the time. The assay must be soldier-friendly (i.e., easy to operate), inexpensive, portable, use heat-stable reagents, and have no special storage requirements.

PHASE I: Selected contractor will determine the feasibility of their proposed concept by developing a prototype diagnostic assay that has the potential to meet the broad needs discussed in this topic. Selected contractor must develop required reagents. Leishmania antigen and Leishmania-infected sand flies can be obtained from the Walter Reed Army Institute of Research (WRAIR). The contractor must provide a single lot of 100 prototypes each for L. major and L. infantum (one assay that can determine either would be preferred) to the COR for initial testing at the WRAIR.

PHASE II: The goal in Phase II is the development of a prototype assay that provides 85% sensitivity for 1 sand fly containing at least 1,000 promastigotes in a pool of 25 sand flies when compared to microscopic examination of sand flies and/or PCR. Each assay should have a specificity of 90% for the species of Leishmania in question. The selected contractor will provide up to 3 initial lots of 500 prototype assays/lot to the COR -- these initial lots will be evaluated at WRAIR for sensitivity and specificity. Feedback regarding the sensitivity/specificity of each lot of prototype assays will be provided to the contractor – this data will then be used to optimize each subsequent lot of assays. The possibility of having 1 assay that could distinguish either species should be considered. Once sensitivity/specificity requirements have been met, the selected contractor will provide a final lot of 1,000 prototype assays for laboratory confirmation of assay performance characteristics (sensitivity, specificity, positive and negative predictive value, accuracy and reliability). Testing for performance characteristics should be done at WRAIR or another facility approved by the COR. The selected contractor will also conduct stability testing of the prototype device in Phase II. Stability testing will follow an accelerated schedule where the contractor will attempt to force the product to fail under a broad range of temperature and humidity conditions and extremes.

PHASE III: The goal of phase III is to validate the prototype product in the field. The selected contractor will provide 10,000 assays to the COR for comprehensive field-testing to ensure that all requirements have been met. Stability testing will be conducted at the WRAIR by performing simple sensitivity and specificity testing on small lots of the protocols every six months over a 2-year period. It is envisioned that field testing will be conducted at the Navy Medical Research Laboratories in Egypt and Peru, at the U.S. Army Medical Research Unit in Kenya, in Iraq by Army PVNTMED DETS, and at other selected sites.

DUAL USE APPLICATIONS: The developed technology could be used by military forces operating in South- and Central America, in Africa, the Middle East, the Mediterranean basis, and parts of central Asia. Local governments or regional commercial medical centers in the developing countries in this region could use this technology to accurately and rapidly assess the threat from leishmaniasis.

COMMERCIAL APPLICATIONS (SPIN-OFF): Government or commercial medical centers and pest control operators in the Leishmania-endemic regions of the world require cheap, easy-to-use diagnostic assays for the detection of leishmaniasis in sand flies. The development of a field-usable Leishmania-assay would provide an urgently needed device that would be commercially viable.

COMMERCIAL APPLICATIONS (SPIN-ON): Development of a technology that meets the military requirement for a device to detect Leishmania major and L. infantum in sand flies could allow for the subsequent development of similar devices for the detection of other diseases of public health and military concern (i.e., leptospirosis or dengue). In fact, an SBIR written in 1995 by LTC Coleman and subsequently directed by LTC Jeff Ryan resulted in the development of the commercially available Malaria Vec-Test as well as West Nile Virus and Saint Louis Encephalitis Virus assays.

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KEYWORDS: Leishmaniasis, Leishmania, Leishmania major, Leishmania infantum, Sand flies, diagnosis, devices

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OSD09-H22 TITLE: Treatment of mTBI Balance Dysfuntion via Multimodal Biofeedback.

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: This topic will develop novel combinations of combined sensory guided feedback to retrain military personnel suffering balance disorders as a result of mild Traumatic Brain Injury.

DESCRIPTION:
Dizziness and vertigo are common in nearly all reported studies of mTBI (mild Traumatic Brain Injury)and appear to contribute disproportionately to disability. A commonly used measure of patient dynamic balance performance across time is the center of gravity measurement while standing on a force plate. The performance varies considerably depending on the sensory feedback available to the patient. Balance performance is based on

information from the sensory systems of vision, audition, vestibular and proprioception (skin, muscle and joint). While testing patients, the visual, tactile and auditory cues are carefully controlled to obtain consistent test results. By providing enhanced sensory feedback cues from multiple systems, the highly plastic nervous system can adapt new motor strategies to improve balance. The physiotherapy community would benefit from a device that optimally combines visual, tactile and auditory feedback to return the patient in the shortest period of time to a level of balance performance consistent with return to community and/or military duty.

PHASE I: Identify the best of each current single sensory feedback treatment that is either currently being used, or could be used, by physiotherapists to enhance balance training. Select one or more feedback systems from each of the visual, tactile and auditory biofeedback modalities that can be integrated with an existing commercial, center-of-gravity measuring device.
Develop a plan for integration of all biofeedback components to include recommended training algorithms as determined from experiments using single biofeedback treatments.

PHASE II: Assemble, test and deliver the prototype system defined in Phase I design. Successful demonstration by the physiotherapy community will provide a market for Phase III development.

PHASE III: The market for commercialization of any product capable of improving balance performance extends well beyond the military mTBI (mild Traumatic Brain Injury) community exposed to blast conditions. In the United States, mTBI accounts for approximately 90 % of the new cases of medically diagnosed head injuries each year. Additionally falls in the rapidly expanding elderly population produce significant morbidity and mortality. The health care system will eagerly accept any tool that provides more rapid rehabilitation of patients. This device will also provide an objective measure of patient progress while undergoing therapy for mTBI related symptoms.

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KEYWORDS: balance, mild Traumatic Brain Injury, mTBI, rehabilitation, biofeedback, multisensory integration, dizziness

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OSD09-H23 TITLE: Advancements in Retinal Imaging for Diagnosis of Mild Traumatic Brain Injury

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop a system using retinal imaging for non-invasive diagnosis of mild TBI patients for use in field hospitals and enroute aeromedical care.

DESCRIPTION: Commotio retinae is a concussion of the retina that may produce a milky edema in the posterior pole that clears up after a few days. Commotio retinae and other eye injury sequalae may be a possible indicator of ocular trauma resulting from blast effects. All previous research of commotio retinae has been on blunt ocular trauma. (1,2) Studies are needed to investigate if noninvasive methods to diagnose commotio retinae may suggest corollary presence of traumatic brain injury resulting from blast effects. Recent technology advances in imaging techniques for evaluation of retinal lesions–hyperspectral imaging, scanning laser, ophthalmoscope (SLO), and ocular coherence tomography (OCT) – may have promise for much more sensitive detection of commotio retinae and correlation to traumatic brain injury particularly when used with other non-invasive diagnostic methods. (3)

PHASE I: Phase I will 1) undertake to establish the correlation of commotio retinae and other eye injury sequalae to traumatic brain injury; and 2) evaluate the increased sensitivity of advanced retinal lesion imaging methods for diagnosing commotio retinae and other retinal injuries that may be correlated to traumatic brain injury.

PHASE II: Phase II will demonstrate the clinical efficacy of a prototype non-invasive retinal imaging device through pre-clinical trials and operational assessments. Efforts will position the enabling technology and corresponding clinical knowledge for application to the targeted patient population and regulatory development of the technology.

PHASE III: Phase III will evaluate in controlled groups the efficacy and safety of the non-invasive diagnostic device for application to the targeted patient population and regulatory development of the technology. It will also investigate dual applications for other neurological disorders such as ischemic or hemorrhagic stroke.

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KEYWORDS: KEYWORDS: commotio retinae, retinal imaging, traumatic brain injury, non-invasive diagnosis

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OSD09-H24 TITLE: Toxicity Sensor for Food

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: The objective is to develop a toxicity sensor that responds rapidly upon exposure to toxic chemicals in foods. This toxicity sensor will permit rapid identification of potential health effects on deployed forces resulting from food-borne exposures to a wide array of toxic chemicals.

DESCRIPTION:
As part of a research program to identify environmental hazards to soldiers resulting from exposure to toxic industrial chemicals, we are seeking new methods for providing rapid toxicity evaluation of foods. Toxicity sensors for water have been proposed (e.g., van der Schalie et al., 2006), but a usable device for foods that overcomes associated technical challenges has yet to be developed. We are seeking innovative and creative research and

development approaches that take advantage of recent advances in cellular and molecular biology to provide a rapid screening test for toxic chemicals in food.

PHASE I: Conduct research to provide a proof of concept demonstration of a toxicity sensor technique for food. The concept will be original or will represent significant extensions, applications, or improvements over published approaches. Design and performance considerations for a proof of concept demonstration are listed below.

1. The toxicity sensor must be responsive to toxicity induced by different modes of toxic action representative of industrial chemicals of military concern. Since there are no set standards in the U.S. for natural limits in foods, accepted drinking water standards (including Military Exposure Guidelines; USACHPPM, 2003) will be used to set the toxicity metric for sensor sensitivity. Those values can be converted to daily doses based on the standard serving size of the foods and the predicted amounts of the foods consumed per day. Endpoint responsiveness should be demonstrated with 3 chemicals (e.g., cyanide, arsenic, and methamidophos) in three food materials: wheat flour/wheat bread, ground beef and whole milk. The chemical will be mixed into the food either using a mixer, grinder or by shaking. Sampling methods will have to be either tested or developed for extracting the chemical from the food matrix for analysis. Appropriate sensitivity will be evaluated with respect to the corresponding toxicity metric; negative responses are expected for control food materials (without added chemicals). Note that the identified test chemicals are intended to be representative of larger classes of chemicals, so analyte-specific sensors for these individual chemicals are not an appropriate solution to this topic.
2. Variability in the statistically-derived test endpoint should be minimized; a coefficient of variation for the endpoint in repeated independent tests should be 15% or less.
3. Toxicity sensor responses must occur within an hour of test initiation.
4. Toxicity sensors that require minimal preparation and processing steps (including sample extraction) and with easily interpreted results are preferred, as are sensors with components with a potential for extended shelf life with minimal environmental requirements.

PHASE II: Expand upon the Phase I proof of concept effort to develop a prototype toxicity sensor for food. Demonstrate sensor sensitivity with respect to appropriate food toxicity metrics based on serving size and consumption and rapidity of response (within an hour) to chemicals representing a wide range of chemical classes and modes of toxic action. The sensor should be designed for straightforward data interpretation, minimal logistical requirements, and maximum storage time of biological components and reagents (if any) prior to use. Demonstrate that the sensor has a low false positive rate in food matrices relevant to Army food supplies.

PHASE III: Evaluate the ability of the toxicity sensor technique to assess the suitability of foods for deployed troops by Military food inspectors or other medical assets under normal military conditions. Field tests will involve testing at an Army Veterinary Food Diagnostic laboratory and Army food depot. Given current on-going concerns regarding accidental or intentional contamination of food supplies, this technology will have broad application for food testing of ingredients and end products by industry as well as state and local governments. A well-formulated marketing strategy will be critical for success in these commercial applications.

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KEYWORDS: rapid toxicity identification, toxicity sensor, toxicity indicator, toxic industrial chemicals, food

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OSD09-H25 TITLE: Remote Diagnostic Access and Automated Proactive Medical Equipment Monitoring in support of Hospital of the Future Initiatives

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop a remote service network capability to conduct diagnostics, calibration, repair and proactive monitoring of medical equipment densities supporting a theater of operations and/or Hospital of the Future initiatives.

DESCRIPTION:
The Army Medical Department has the urgent requirement for a remote diagnostic capability in support of the configuration and/or troubleshooting of medical equipment densities supporting a theater of operations and/or Hospital of the Future initiatives providing safe, cost effective, predictive, preventative and evidenced based healthcare.

Sophisticated and complex medical equipment, frequent rotations of biomedical equipment technicians, their associated level of training coupled with considerable downtime of critical medical equipment densities has hampered health care support to our warfighters.

The need exists to develop a virtual medical maintenance capability which has the ability to link to the present medical communications for combat casualty care (MC4) architecture; provide a configurable firewall to protect from unauthorized access; integrate virus protection; transparent network integration; and the provision for a VPN router for secure data transmission. Additionally, the requirement exists to conduct remote diagnostics, calibration, and repair of theater medical equipment in order to facilitate the life cycle management policy. The remote maintenance capability must support the electronic transmission of video/audio data; access for remote technician field support; provide for limited on-site visits if required; sustainment of a historical information database; and support the integration of emerging medical maintenance technologies.

Tele-Maintenance has the following benefits:
• Optimizes personnel resources: transports the knowledge not the individual; enhances split-based operations; and supports multiple contingency operations.
• Increases readiness: compresses time of repair; reduces number of Depot-level repairs; and provides timely maintenance information to the soldier by taking advantage of the Internet.
• Cost savings: decreases unnecessary component replacements; eliminates temporary duty travel to field locations

PHASE I: This phase will focus on the investigation of information systems/technologies supporting the remote management of medical technologies supporting the theater of operations. The desired deliverable is a matrix outlining the medical maintenance requirements and the associated technologies supporting the remote diagnostic capability of that requirement. The matrix will be inclusive of user roles and responsibilities; policies and procedures and training. This matrix will be used to determine the initiatives" feasibility, functionality and the development of courses of action.

PHASE II: Based on the decision matrix developed in phase I, the objective of phase II is the design and integration of a prototype technology which provides remote diagnostic access capability enabling troubleshooting and problem resolution associated with medical equipment densities. This phase will also demonstrate proactive monitoring capabilities which systematically access the medical equipment to monitor its operating statistics. The resulting phase II prototype will be used to support the maintenance mission of the US Army Medical Materiel Agency and its supporting bio-medical equipment technicians. The prototype will integrate with the Department of Defense Information Management systems as well as the Medical Communication for Combat Casualty Care architecture.

PHASE III: The research goal is to develop an enterprise-wide remote service and monitoring capability inclusive of a knowledge management database which processes the collective information stored within it to provide statistical data for logistics decision makers. A potential commercial application of this technology would be the enhancement of the current medical device business models incorporating remote servicing/ diagnostics to reduce the costs of service contracts.

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Topic: Military Logistics Management
4. http://www.almc.army.mil/alog/issues/SepOct05/maintennanceRev.html

KEYWORDS: tele-maintenance, remote diagnostics, monitoring, information management

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OSD09-H26 TITLE: Novel Methods to Monitor Health Status and Clinical Laboratory Data: Portable Acquisition, Assessment, and Reporting of Middle Ear Function and Hearing

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop a clinical unit for assessing middle-ear function, hearing, and otoacoustic emissions (OAEs) within the same insert earphone specifically for hearing-conservation programs (HCPs).

DESCRIPTION: Warfighters are exposed to noise environments that exceed commercial exposures in intensity, duration, and lack of adequate recovery time. Hearing-protector use is not widespread enough, and current protectors are not fully adequate against jet noise, gunfire, and explosives. Thus, noise-induced hearing loss is pervasive. The technology that is used today in HCPs is very old and rudimentary and does not take advantage of newer developments such as measurements of middle-ear status and measurement of otoacoustic emissions (OAEs), (which, if administered with the proper paradigms and quality controls, can be developed to allow the monitoring audiologist to evaluate HCP effectiveness and identify problems in the HCP that will not be apparent with pure-tone audiometry, may identify individuals who are most susceptible to noise-induced hearing loss, and can be developed as an aid to screening for malingerers). Also, current technology has inadequate calibration, quality controls, and tester feedback to insure quality tests, even for pure-tone testing. The calibration often is based on acoustic coupler measurements rather than individual ears, and, even when individual measurement is incorporated, the technology does not adequately estimate the actual sound input at the eardrum, which is important in the frequency regions that are most susceptible to noise-induced hearing loss. Furthermore, existing equipment in the hands of hearing-conservation technicians, rather than researchers or audiologists, often gives results with inferior reliability and validity, along with creative interpretation of the data and management of the cases.

At present, annual monitoring of hearing primarily demonstrates the failure of the HCP for particular individuals (i.e., a rather large, irreversible permanent shift in hearing). No instrumentation currently exists to measure otoacoustic emissions and middle-ear function specifically for hearing-conservation purposes, nor are there any sophisticated all-in-one devices. To improve hearing-conservation efforts, the proposed topic seeks to develop sensitive measurements using an individually calibrated insert earphone, which provides some resistance to external sounds, and a controller programmed to deliver a sequence of tests and display results in ways that make sense for hearing-conservation programs and that can be administered by enlisted medical personnel. This new technology will be more reliable, and should be able not only to identify smaller changes in hearing, but also to identify some of the precursors to noise-induced hearing loss (NIHL), as well as screen for malingering using a combination of OAEs and new behavioral tests. Administratively, inadequate HCPs can be identified more quickly, the individuals who may be artificially inflating their hearing thresholds for personal reasons can be more readily identified for audiological referral, and the individuals most at risk for NIHL can be followed more aggressively and individually (with the potential for those at lower risk to perhaps have less frequent follow-up). It will not be possible to make these improvements to HCPs unless the equipment can be developed for it.

PHASE I: Identify candidate technologies and procedures that are capable of measuring hearing, otoacoustic emissions, and middle-ear function in the same all-in-one equipment. Middle-ear testing must not only give decisions about referrals for potential middle-ear problems, but also muxt provide validation of the OAE testing, and should include a range of frequencies. For measurements of middle-ear pressure, the advantages and disadvantages of using the same probe microphone, rather than a separate probe microphone should be considered. In either case, the same controller should be used for middle-ear testing and all the other tests. Automated pure-tone threshold testing can implement current standard procedures or may use other psychophysical procedures –all must have: (1) a standard error of measurement no larger than that obtained in laboratory studies of standard audiometric procedures; (2) analysis of inconsistent responses; (3) an average duration of no more than 40 sec per test frequency; (4) and be no more susceptible to malingering than are current audiological procedures. Novel psychoacoustical techniques based on the loudness of thresholds for tones versus noise bands or speech should be developed for automated tests of malingering. The OAE equipment must provide at least two different types of OAE stimuli – one should be TEOAEs, and the other should be tonal. It must be possible to measure the medial olivocochlear reflex with a contralateral activator. The system must be binaural. Calibrations for all tests (behavioral, OAE, and middle-ear) must be made in each individual ear, and development of technology to address the validity of the calibration for frequencies above 2-3 kHz must be considered. In-the-canal, frequency-specific noise measurements must be used to determine the validity of testing. The hearing and OAE results must be configured so that they can be monitored over time using administrative user-selected criteria (at the level of the supervisory-audiologist program manager, not at the technician level). It must also be possible for the administrators to establish data flags for pass-fail criteria for each hearing, middle-ear, and OAE test to warrant referral to an audiologist. Furthermore, there must be in-built quality-control assessments with feedback to the HCP technician about how to improve the quality of the measurement, drop-down menus that require adequate descriptions of most recent noise exposure before testing can begin, and technician feedback about interpretation of the results. Some of the technology exists, but there are challenges in calibration; microphone sensitivity and allowable noise floors that are suitable for all the measurements; psychoacoustical procedures; on-site, automatic decision-making for all cases; and centralized, programmatic decision-making for assessment of HCP adequacy.

The overall system design must be flexible to accommodate the development of future assessment strategies (particulary in the area of OAEs, middle-ear testing, analyses used for decision-making, and feedback provided to operators and administrators) and other software modifications. Consultation with the military hearing-research and occupational-audiology community is required.

PHASE II: Develop and demonstrate a prototype system in a realistic military environment. Conduct testing to prove feasibility including system reliability (e.g., individual variability over repeated assessments), validity, and ease of use. Demonstrate connectivity/reporting features in concert with existing databases or cost-effective alternatives.

PHASE III: This system could be used in a broad range of military and civilian HCP applications Develop a fully deployable product that is market-ready for the research, clinical, and military communities. Establish collaborative relationships with these communities to address future product developments.

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KEYWORDS: noise-induced hearing loss, NIHL, hearing loss, otoacoustic emissions, OAE, assessment, tracking, middle ear function, hearing-conservation programs, HCPs.

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OSD09-H27 TITLE: Development and commercialization of a tent trap for the surveillance and control of disease-carrying flies

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop and evaluate a commercially viable tent suction trap that uses human attractant in a non-hazardous manner for the surveillance and control of mosquito, midge and sand fly disease vectors.

DESCRIPTION: Background: Insect-borne diseases such as malaria, dengue and leishmaniasis pose a significant threat to deployed military forces (e.g. Burnette et al. 2008). Intelligence about the insect species responsible for vector-borne diseases in a given area requires the vectors to be captured and identified. We believe that the development of a human-baited tent trap for the surveillance and control of biting flies would help fill an important capability/technology gap for the military.

Traditionally, entomological surveys involved collecting blood-seeking flies, such as mosquitoes, as they came to bite human volunteers. Much research has gone into developing traps that mimic the odours, heat and carbon dioxide (CO_2) output of humans. For example, the Centers for Disease Control (CDC) trap now uses a canister of dry-ice to produced CO_2, and a battery operated fan to suction mosquitoes into a holding receptacle (Newhouse et al. 1966). Mosquito traps vary in the abundance and types of mosquito species caught, and provide operational challenges for field deployment, for example where a local source of CO_2 is not available. For epidemiological and operational reasons human-baited insect trapping may have advantages over mechanical trapping, but is no longer permitted due to concerns for the human bait. One solution could be the development of a tent trap. Regular removal trapping of insect vectors by tent traps may even act to suppress populations of vectors in an area.
Service (1976) reviews the various types of mosquito traps that have been developed. One design uses an internal net housing a sleeping human and an outer net raised at the bottom to allow mosquitoes access. Collectors regularly aspirate the mosquitoes caught between the nets or a suction fan is placed inside the top of the outer net to capture

mosquitoes. The problem with these designs is that they are either not efficient or are erected in an ad hoc manner, with the result that they have not gained widespread acceptance.

The goal of this SBIR is to successfully develop an easily erected, freestanding 1-2 person tent that is modified to capture biting flies that come to bite a human resting inside. The tent would incorporate an internal suction fan and holding container that collects mosquitoes caught between the internal net housing the human bait, and the tent rainfly or outer covering. The use of an internal fan would act to disperse the human heat, odour and CO_2 attractants from the tent out through net covered vents. The fan will also make sleeping in the tent more comfortable in tropical environments.

PHASE I: The selected contractor determines the feasibility of the concept by developing a working model of the tent trap, possibly by adapting a commercially available tent and CDC mosquito trap. One possible trap design relies on host-seeking mosquitoes that reach the mesh vents moving upwards into a dark, enclosed conical space between fly and tent, the apex of which houses the end of a inlet hose connected to the fan trap. Mosquitoes reaching the zone of negative pressure near the inlet hose are sucked into the holding container inside the tent, enabling easy removal at the end of the night. The fan could be based on commercially available models that use a solar rechargeable 6 volt battery (e.g. http://www.johnwhock.com/resources/tutorial_batteries.htm). Ideally, the tent trap should be as efficient as the traditional human bait method for trapping mosquitoes.

PHASE II: The goals of Phase II are the production of a prototype, field testing this prototype to determine its efficiency, and fine-tuning the design prior to developing a commercial-ready product. Specific goals for testing the prototype include demonstrating: i) that the tent trap collects a similar spectrum of mosquito species compared to a human bait and a CO_2 trap, ii) that the tent trap collects similar numbers of mosquitoes to a human bait and a CO_2 trap, iii) that the tent trap captures other sorts of biting flies such as sand flies and biting midges, iv) that the tent trap fulfills the ethical requirements for the use of humans in mosquito research (i.e. minimizes the risk of exposure to insect bites), and v) that the tent trap is robust enough for field operation on a long term basis. The degree to which the prototype tent meets the desired capability outlined above will be evaluated by a government laboratory. The Walter Reed Army Institute of Research may be able to provide support to Phase II efforts. Support could include access to technology (i.e. information on mosquito species identification) as well as testing and evaluation of candidate tent designs. All requests for support should be coordinated thru the topic author and/or COR well in advance of the date that the support is required. Data from this independent evaluation will be used in the determination of the Phase III awardee.

PHASE III: The tent trap developed under this SBIR topic will be suitable for use in a variety of military entomology units for surveillance of insect vectors of disease. The potential for widespread deployment of this trap to suppress mosquito and sand fly vector populations and disease transmission could be a potential future research direction. Tent traps will also be available for non-military medical purposes, such as use by regional mosquito control authorities or non-governmental organizations (NGOs) in areas of the world where entomological surveys of mosquitoes and sandflies are carried out. We envision that the Tent trap, or a version of this, will be able to be marketed to a variety of commercial entomology organizations, and possibly camping outlets, and that this market will be adequate to sustain the continued production of these products.

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KEYWORDS: Tent, trap, human bait, host-seeking, vector-borne disease, pest control

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